UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

MAYOR & CITY COUNCIL OF BALTIMORE,
City Hall
100 N. Holliday St.
Baltimore, MD 21202

Plaintiff,

v.

ELI LILLY AND COMPANY,
740 South Alabama Street
Indianapolis, IN 46225

NOVO NORDISK INC.,
800 Scudders Mill Road
Plainsboro, NJ 08536

SANOFI-AVENTIS U.S. LLC,
55 Corporate Dr.
Bridgewater, NJ 08807

EVERNORTH HEALTH, INC. FKA EXPRESS SCRIPTS HOLDING COMPANY,
1 Express Way
St. Louis, MO 63121

EXPRESS SCRIPTS, INC.,
1 Express Way
St. Louis, MO 63121

EXPRESS SCRIPTS ADMINISTRATORS, LLC,
1 Express Way
St. Louis, MO 63121

EXPRESS SCRIPTS PHARMACY, INC.,
1 Express Way
St. Louis, MO 63121

ECF CASE

No. _____

COMPLAINT

JURY TRIAL DEMANDED

ESI MAIL PHARMACY SERVICE, INC.,
1 Express Way
St. Louis, MO 63121

MEDCO HEALTH SOLUTIONS, INC.,
100 Parsons Pond Dr.
Franklin Lakes, NJ 07417

CVS HEALTH CORPORATION,
1 CVS Dr.
Woonsocket, RI 02895

CVS PHARMACY, INC.,
1 CVS Dr.
Woonsocket, RI 02895

CAREMARKPCS HEALTH, LLC,
1 CVS Dr.
Woonsocket, RI 02895

CAREMARK RX, LLC,
1 CVS Dr.
Woonsocket, RI 02895

CAREMARK, LLC,
2211 Sanders Rd.
Northbrook, IL 60062

UNITEDHEALTH GROUP, INC.,
9900 Bren Road East
Minnetonka, MN 55343

OPTUM, INC.,
11000 Optum Circle
Eden Prairie, MN 55347

OPTUMRX INC.,
2300 Main Street
Irvine, CA 92614

OPTUMINSIGHT, INC.,
13625 Technology Dr.
Eden Prairie, MN 55344

Defendants.

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Plaintiff, the Mayor & City Council of Baltimore ("Baltimore"), brings this action against the above-named Defendants: Eli Lilly and Company; Novo Nordisk Inc.; Sanofi-Aventis U.S. LLC; Evernorth Health, Inc. fka Express Scripts Holding Company; Express Scripts, Inc.; Express Scripts Administrators, LLC; Express Scripts Pharmacy, Inc.; ESI Mail Pharmacy Service, Inc., Medco Health Solutions, Inc.; CVS Health Corporation; CVS Pharmacy, Inc.; CaremarkPCS Health, LLC; Caremark Rx, LLC; Caremark, LLC; UnitedHealth Group, Inc.; Optum, Inc.; OptumRx Inc.; and OptumInsight, Inc., and alleges the following based on personal knowledge, information and belief, and the investigation of counsel:

I. INTRODUCTION

1. Baltimore brings this action to hold Defendants accountable for their roles in artificially manufacturing the skyrocketing prices of insulin and other diabetes medications through a pernicious multi-billion-dollar scheme (the "Artificial Pricing Scheme") in which the drug manufacturers raised list prices to provide the pharmacy benefit managers ("PBMs") with increased kickback payments, rebates, and other compensation and buy their way onto the PBMs' valuable formularies.

2. This vicious cycle of price increases in order to ensure increased rebates and other payments for PBMs has resulted in the same drugs that sold for $20 shortly after their development and approval selling for more than $300 two decades later.

3. Baltimore, like other health plan payors and consumers, has been directly and predictably harmed by this scheme by being forced to pay unjustifiably inflated prices for diabetes medications. But not all payors bear the brunt of Defendants' scheme equally. Diabetes is a disease that disproportionately impacts minority communities, the African American community in particular. As a majority African American city, Baltimore is particularly affected by the

artificially inflated prices for diabetes treatments as it contributes to providing these life-saving medications to its employees, retirees, and other beneficiaries. Indeed, while in the United States approximately 10% of the population has been diagnosed with diabetes, in Baltimore the rate is 30% higher, with 13% of the population diagnosed.

4. The raw dollar figures—as substantial as they are—spent on the inflated prices reflect just some of the harm this scheme has done to Baltimore. The inflated costs for Defendants' medications siphon resources from Baltimore's overall budget, reducing Baltimore's ability to devote resources to other crucial services for its citizenry.

5. Increased prices for diabetes medications have also, predictably, resulted in "rationing"—where diabetics delay in refilling prescriptions, skip doses, or take smaller doses than needed to manage the costs associated with diabetes drugs.[1] Rationing, in turn, can result in the same outcomes as untreated diabetes, including death caused by Diabetic Ketoacidosis. Such outcomes, which are preventable when diabetics are able to access their insulin in the proper doses, place additional strains on emergency services and medical facilities, including those managed by Baltimore.

6. The "Big Three" suppliers of diabetes medications in the United States (and globally), Defendants Novo Nordisk, Sanofi-Aventis, and Eli Lilly (together "Manufacturer Defendants"), collectively have a stranglehold on the market. Historically, these three companies have controlled 92% of the global market share for insulin products by volume and 96% of the global market share for insulin products by revenue.[2] They also sell some of the most popular GLP-1 medications for Type 2 diabetes treatment.

[1]Linda Searing, *Over 1 Million Americans with Diabetes Rationed Insulin in Past Year*, Washington Post (Nov. 8, 2022), https://www.washingtonpost.com/wellness/2022/11/08/diabetes-insulin-rationing/.
[2]Ryan Knox, *Insulin insulated: barriers to competition and affordability in the United States insulin market*, 7 J. Law and the Biosciences (Oct. 9, 2020), https://academic.oup.com/jlb/article/7/1/lsaa061/5918811.

7. The three largest pharmacy benefit managers in the United States, Defendants Express Scripts, CVS, and OptumRx (together, "PBM Defendants"), have a similarly strong hold on the PBM market—controlling approximately 80% of the U.S. market. And through vertical integrations, these PBMs are also owned and controlled by the same entities that own some of the largest pharmacies and insurance companies in the country.

8. The interlocking corporate family of Express Scripts, for example, includes Cigna and controls approximately 24% of the PBM market, 11.2% of the pharmacy market, and 10% of the commercial insurance market. Similarly, CVS's corporate family includes Aetna and controls approximately 33% of the PBM market, 25% of the pharmacy market, and 11% of the commercial insurance market. And OptumRx is affiliated with UnitedHealth and controls approximately 22% of the PBM market, 7% of the pharmacy market, and 14% of the commercial insurance market.[3]

9. These conglomerates are all within the top 20 of the Fortune 500 list of the highest-revenue-generating companies in the United States. UnitedHealth Group is 5th on the list with $324,162,000,000 in revenue. CVS Health is 6th with $322,467,000,000 in revenue. And Cigna Group is 15th with $180,516,000,000 in revenue.[4]

10. With their vast market share in the PBM industry, bolstered by their associations with and/or control of some of the most powerful pharmacies and insurers, Defendant PBMs wield enormous power in determining what diabetes medications are available to consumers. PBMs do this largely by establishing what are called formularies (colloquially known as approved drug lists)

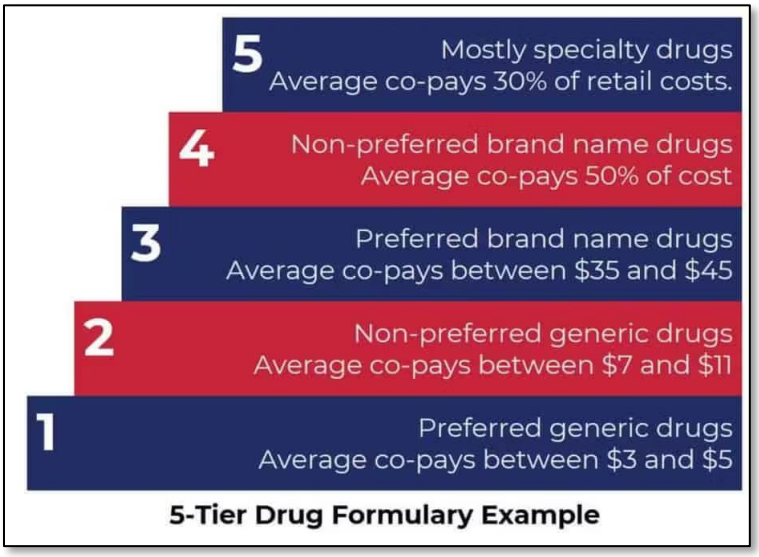
[3]Paige Twenter, *Top PBMs by 2022 market share*, Becker's Hospital Review (May 23, 2023), https://www.beckershospitalreview.com/pharmacy/top-pbms-by-2022-market-share.html; Adam J. Fein, *The Top 15 U.S. Pharmacies of 2022: Market Share and Revenues at the Biggest Companies*, Drug Channels (Mar. 8, 2023), https://www.drugchannels.net/2023/03/the-top-15-us-pharmacies-of-2022-market.html; *AMA identifies market leaders in health insurance*, AMA (Dec. 12, 2023), https://www.ama-assn.org/press-center/press-releases/ama-identifies-market-leaders-health-insurance#:~:text=UnitedHealth%20Group%20(14%25)%2C%202,Cigna%20(10%25)%2C%205.

[4]*Fortune 500*, Fortune, https://fortune.com/ranking/fortune500/search/ (last visited Feb. 13, 2023).

for their clients. Formularies determine which medications are covered and which are not, the amount of out-of-pocket costs for beneficiaries, and other restrictions on covered access to the medications.

11. Having their medications included on the PBM Defendants' formularies with favorable terms (*i.e.*, low out-of-pocket costs and few or no restrictions) is extremely valuable to the Manufacturer Defendants as it directly correlates to their ability to sell their medications. Inclusion on the PBMs' formularies means that the medication is accessible for the millions of beneficiaries on plans managed by the PBMs. Exclusion makes a medication inaccessible for most beneficiaries, particularly where medications offering a similar function are included on the list. But the decisions are not only between inclusion and exclusion; out-of-pocket costs for drugs for beneficiaries are determined by what "tier" a drug is assigned on the relevant formulary.[5]

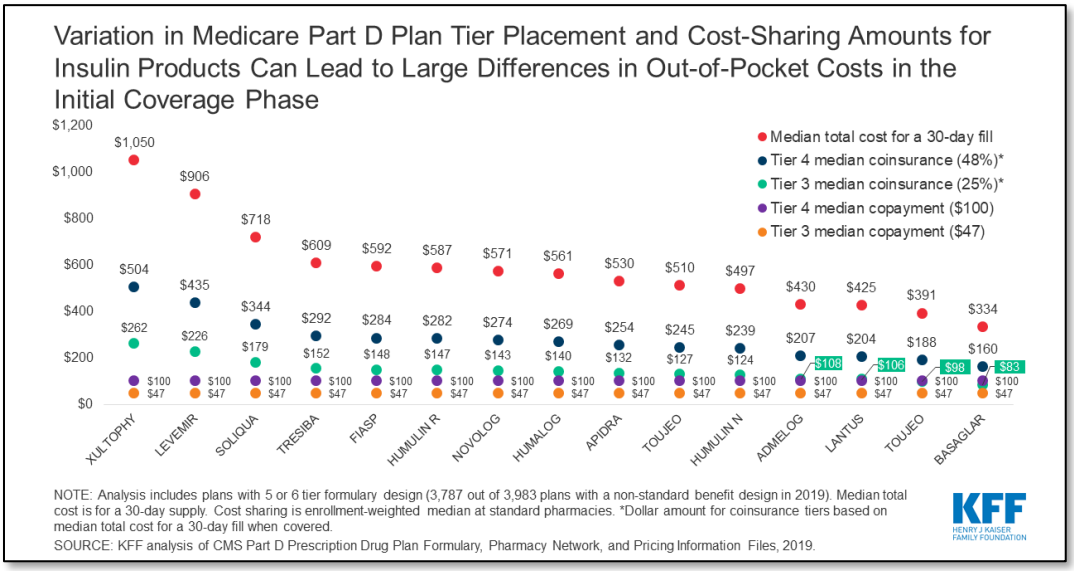
Figure 1 - Formulary Example



[5]Kolt Legette, *Drug Tiers: Understanding Your Part D Costs*, ClearMatch Medicare (Jan. 17, 2022), https://clearmatchmedicare.com/blog/medicare/drug-tiers.

12. The below chart, for example, shows the disparity in prices for beneficiaries depending on how certain insulins are designated on formularies.[6] Better designations on formularies lead to lower out-of-pocket costs for patients and, in turn, a greater likelihood that patients will opt for the selected variety of insulin (if appropriate for their treatment).

Figure 2 - Insulin Price Changes by Formulary Designation



13. The Artificial Pricing Scheme arises from this intersection between Defendants' control over the market in their respective industries—diabetes medication manufacturing and PBM services.

14. The prices of the Manufacturer Defendants' insulin have soared, particularly in recent years. Humalog, for instance, cost just $21 in 1999. In 2019, that same medication cost $332—a nearly 1500% increase.[7]

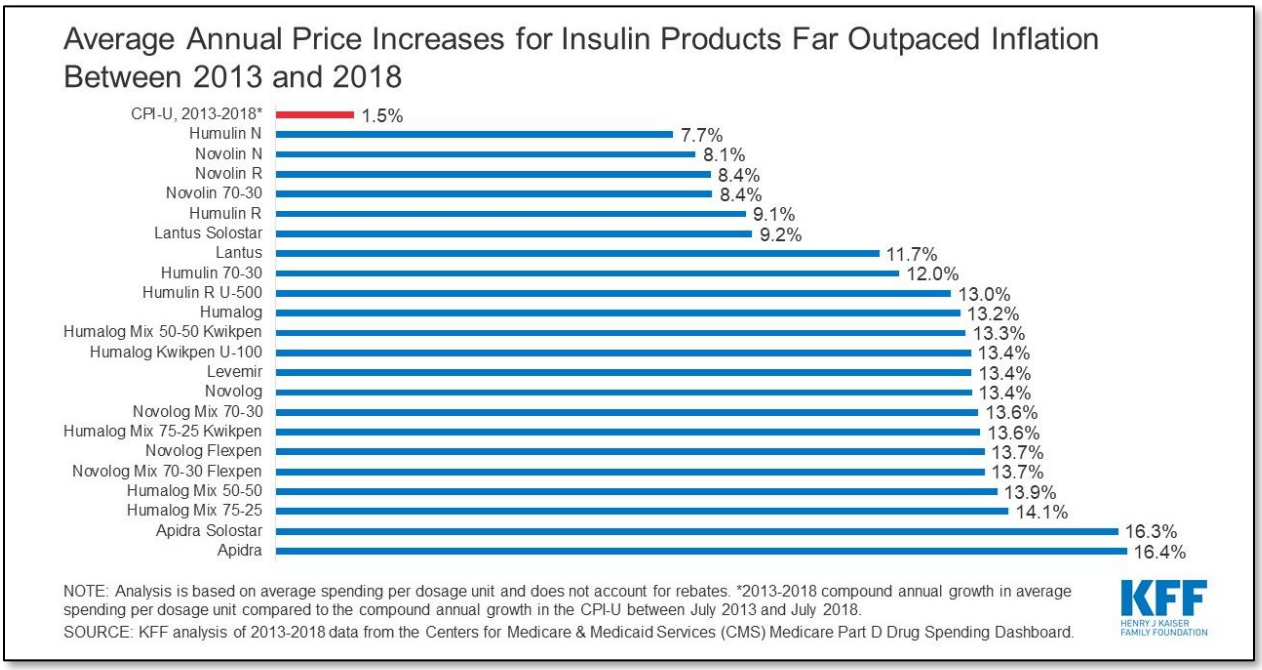
[6]Justin Cubanksi, et al., *Insulin Costs and Coverage in Medicare Part D*, KFF (Jun. 4, 2020), https://www.kff.org/medicare/issue-brief/insulin-costs-and-coverage-in-medicare-part-d/

[7]Brenna Miller, *After decades of profiteering, insulin manufacturer finally cuts the price*, Lown Inst. (Mar. 2, 2023), https://lowninstitute.org/after-decades-of-profiteering-insulin-manufacturer-finally-cuts-the-price/#:~:text=Just%20twenty%20years%20later%2C%20the,rationing%20or%20foregoing%20their%20medication.

15. Other medications have also seen extreme increases in price. Between 2000 and 2018, the price of Novolog, for example, rose around 403% to around $289 per vial. And the price of Lantus rose approximately 420%, adjusting for inflation, to $276 per vial between 2000 and 2019.[8]

16. As shown by the below chart, prices for insulin products have increased at a rate far exceeding inflation.[9]

Figure 3 - Insulin Price Increases vs. Inflation



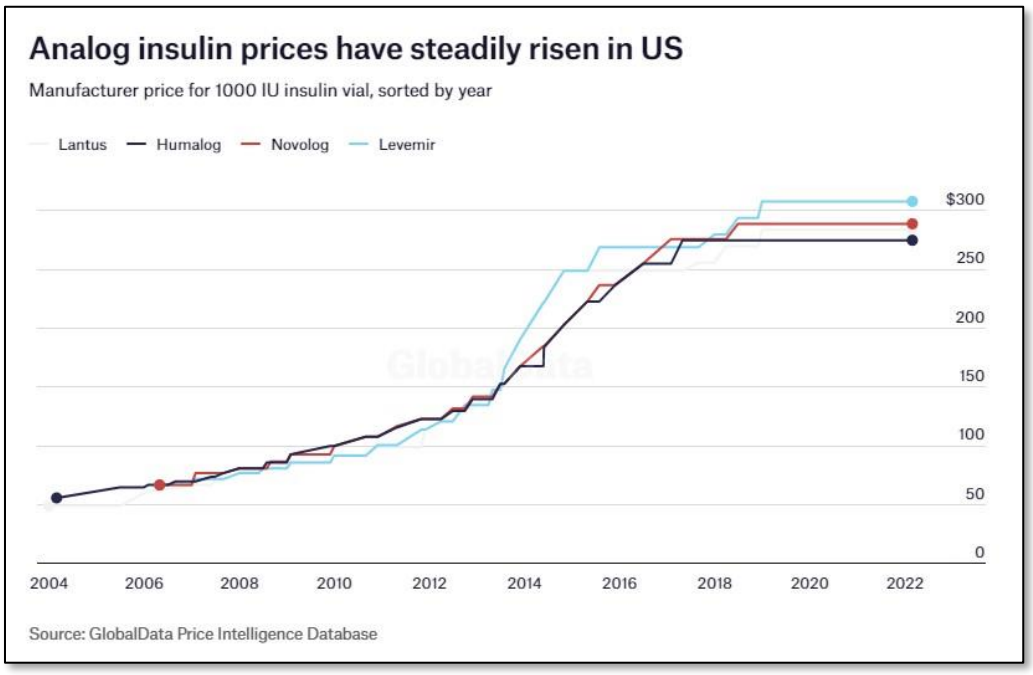
17. Beyond being extreme, the Manufacturer Defendants' price increases have also been done in lockstep. As discussed in a Senate Finance Committee report on the rising cost of

[8]Matt McConnell, *"If I'm Out of Insulin, I'm going to Die": United States' Lack of Regulation Fuels Crisis of Unaffordable Insulin*, Human Rights Watch (Apr. 12, 2022), https://www.hrw.org/report/2022/04/12/if-im-out-insulin-im-going-die/united-states-lack-regulation-fuels-crisis.
[9]Cubanski, et al., *supra* note 6.

insulin, Manufacturer Defendants have increased prices mirroring one another within "days or even hours."[10]

18. The below graph, for example, highlights the extreme and coordinated price increases for some analog insulin products manufactured by the Manufacturer Defendants: Lantus (Sanofi), Humalog (Eli Lilly), Novolog (Novo Nordisk), and Levemir (Novo Nordisk).[11]

Figure 4 - Rising List Prices of Analog Insulins



19. Normal market factors cannot explain these coordinated and extreme price hikes. Manufacturing costs for insulin remain low: it takes less than $10 to produce a vial. And not much about the medications has changed as prices have skyrocketed. Other than the price, the $300 vial of Humalog is, in essence, the same as the $20 vial of Humalog sold when the medication was first

[10]*See* Charles E. Grassley & Ron Wyden, *Staff Report on Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug*, *Sen. Fin. Comm.*, at 6, (Jan. 2021), https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf (hereinafter "Grassley & Wyden Report").
[11]William Newton, *Insulin Pricing: could an e-commerce approach cut costs?* Pharmaceutical Technology (Mar. 31, 2022), https://www.pharmaceutical-technology.com/features/insulin-pricing-could-an-e-commerce-approach-cut-costs/

approved. And the typical excuse for rising prices by pharmaceutical companies: investment into "research and development," has been repeatedly disproven.[12]

20. Rather, increased prices stem from the Artificial Pricing Scheme.

21. The relevant players in the Artificial Pricing Scheme are the Manufacturer and PBM Defendants. In this lawsuit, the relevant victim of the scheme is Baltimore, though other payors and consumers have been harmed by the scheme as well.

a. **Baltimore**: Baltimore operates a self-funded insurance plan for its beneficiaries (employees, retirees, and dependents). This includes pharmacy benefits, through which Baltimore pays a large share of the price of the cost of pharmaceuticals for its beneficiaries. Baltimore used Express Scripts as a pharmacy benefit manager from 2006-2017 and CVS from 2018 to the present.[13]

b. **Manufacturers**: The Manufacturer Defendants (Eli Lilly, Sanofi, and Novo Nordisk) produce medications, including the subject diabetes medications.[14] They set the price for those products. The price of pharmaceuticals is described in various ways. The Wholesale Acquisition Cost (WAC) is defined, per law, as "the manufacturer's list price for [a] drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price . . . ." 42 U.S.C. § 1395w-3a(c)(6)(B). This is also

[12]*See* Grassley & Wyden Report, *supra* note 10 at 17; *Drug Pricing Investigation: Majority Staff Report*, Committee on Oversight and Reform U.S. House of Representatives at xv, 168-171 (December 2021), https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf (hereinafter "Oversight Report").

[13]From 2018 to 2021 Baltimore utilized CVS Caremark as a PBM in conjunction with its use of CareFirst, a pharmacy care program by Blue Cross Blue Shield.

[14] In this Complaint, "subject diabetes medications" or "subject diabetes drugs" refers to Humulin R, Humulin R 500, Novolin R, Humulin N, Humulin 70/30, Novolin N, Novolin 70/30, Humalog, Novolog, Fiasp, Apidra, Lantus, Levemir, Basaglar, Toujeo, Tresiba, Victoza, Trulicity, Ozempic, and Soliqua.

occasionally referred to as the list price. The WAC or list price is the price upon which prices throughout the supply chain are ultimately based.

c. **PBMs**: The PBM Defendants (CVS, Express Scripts, and OptumRx) are engaged by insurers, like Baltimore, to manage their pharmacy benefits. PBMs do so, in part, by negotiating with drug manufacturers. PBMs also work with pharmacies to fill prescriptions for plan beneficiaries. As previously discussed, PBMs maintain formularies, which give them a strong negotiating lever that they could (indeed, should) use to ensure affordable medication prices for their payor customers. Payors, like Baltimore, compensate PBMs by allowing them to retain a portion of certain discounts negotiated with drug manufacturers and through fees, such as those related to filed and filled pharmacy claims or other services.

22. In a competitive market, one would expect competition among manufacturers for inclusion on PBM formularies to lead to lower drug prices. For the subject diabetes medications, however, the opposite has occurred. Pressure from the PBM Defendants has led the Manufacturer Defendants to artificially increase list prices (untethered from the actual value of these drugs) so that they can kickback increased portions of the inflated values to the PBMs in exchange for favorable treatment on their formularies. These payments, called "rebates and other payments" in this Complaint, come in various forms: administrative fees, rebates, discounts, credits, concessions, and so on.

23. The various labels for these payments have enabled PBMs to avoid paying (or even providing an accounting of) the full amounts to payors, who are, in some cases, promised under their agreements with the PBMs to be remitted some percent of the "rebates" or other specific categories of payments negotiated by PBMs. These shifting labels also prevent the detection of

the Artificial Pricing Scheme as designating these payments as something other than "rebates" helps PBMs to avoid their disclosure through the narrowly defined audit rights contractually provided to some payors.

24. Accordingly, the full extent of the rebates and other payments from Manufacturer Defendants to PBM Defendants is unknown. But what is known is that the scheme results in a vast difference between Manufacturer Defendant list prices and the amounts received once all payments to PBMs are accounted for (the "net price"). This results in both PBM Defendants and Manufacturer Defendants receiving compensation far beyond the true value of the drugs and services they provide.

25. This scheme represents a win-win for Defendants. PBMs get exorbitant amounts based on Manufacturer list prices and Manufacturers increase revenues by being favorably placed on formularies. As PBMs get larger rebates, Manufacturers simply increase their list prices.

26. Accordingly, the Manufacturer Defendants' list prices are false and inflated prices, untethered to the actual value of their drugs (indeed, far exceeding the net prices of the drugs) and not the result of any legitimate competition for the business of payors. These prices, reported by Manufacturer Defendants to companies that compile and publish pharmaceutical prices (such as Redbook and Medi-Span), are simply a reflection of the artificial inflation done by the Manufacturer Defendants in furtherance of the Artificial Pricing Scheme.

27. Rather than use their market power to lower drug prices for their customers, as they promise and claim to do, PBM Defendants instead make their formulary decisions based on high list prices and the rebates and other payments they receive from the Manufacturer Defendants. The PBM Defendants do this to the detriment of payors like Baltimore and their beneficiaries, whose payments are based on the list price of drugs. PBMs fail to disclose this fact to payors, nor

do they disclose that, rather than act to save payors money—as they advertise—Defendant PBMs are doing the opposite, working instead to line their own pockets at the expense of their customers. Nor do PBM Defendants disclose their role in ultimately driving the prices of diabetes medications up (rather than down).

28. By driving up the price of diabetes medications through the unfair and deceptive Artificial Pricing Scheme, Defendants have directly harmed all who contribute to the purchase of diabetes medications, including Baltimore.

29. Baltimore has been considerably overcharged as a direct result of the Artificial Pricing Scheme.

30. Accordingly, through this action, Baltimore seeks injunctive relief, actual damages, restitution, disgorgement, attorneys' fees and costs, and any and all other relief available to remedy the direct and foreseeable harms caused (and those that continue to accrue) as a result of the Artificial Pricing Scheme and Defendants' violations of Federal and Maryland law.

31. The relevant period for damages alleged in this Complaint is from 2006 to the present.

II. THE PARTIES

A. Plaintiff

32. Plaintiff is the Mayor & City Council of Baltimore, a municipal corporation organized and existing under the laws of the state of Maryland. The City Solicitor has the "sole charge and direction of the preparation and trial of all suits, actions and proceedings of every kind to which the City . . . shall be a party." Baltimore City Charter Art. VII § 24(b).

33. Baltimore has a population of over 500,000. More than 60% of Baltimore's population is African American.

34. As the municipal corporation responsible for this population and the city itself, Baltimore provides several essential services. Such services include, among other things, public transportation, public safety, health services, city planning and management, recreational opportunities, and education.

35. Providing these services requires employees, and Baltimore currently employs more than 14,000 individuals.

36. As a benefit to many of its employees, retirees, and their dependents, Baltimore offers health benefits. Baltimore acts as a self-insurer in providing these benefits. In total, Baltimore provides its self-insured health benefits to more than 60,000 individuals ("Beneficiaries").

37. These health benefits include pharmaceutical benefits through which Baltimore pays a sizable portion of many of its beneficiaries' medication costs.

38. The cost of insulin, along with other Type 2 diabetes medications, for beneficiaries represents a large expense for Baltimore. Particularly so as the prices for these medications have skyrocketed, outpacing inflation and the rising costs of other goods, on account of Defendants' misconduct. Baltimore pays more than $11,000,000 in gross costs per year for diabetes medications alone.

39. The increases in spending attributable to such costs affects other aspects of Baltimore's budget. Every dollar spent on inflated prices for diabetes medication is one Baltimore cannot spend in other ways to benefit the city and its residents.

40. In this action, Baltimore seeks relief for the harm it has suffered from Defendants' misrepresentations, omissions, and involvement in the scheme to unjustifiably inflate the prices of the subject diabetes medications.

B. Manufacturer Defendants

41. As previously discussed, Eli Lilly, Novo Nordisk, and Sanofi manufacture the lion's share of insulin and other diabetes medications. Measured by either volume or revenue, these three companies control over 90% of the global market for insulin.[15]

1. Novo Nordisk

42. Defendant Novo Nordisk Inc. ("Novo Nordisk") is a Delaware corporation with a principal place of business in New Jersey.

43. Novo Nordisk is registered to do business in Maryland. That registration was made in 2010.

44. Novo Nordisk manufactures, promotes, and distributes a number of the subject diabetes medications in Maryland and throughout the United States. These medications include: Novolin R and Novolin N (human insulins approved in the United States in 1991); Novolog (analog insulin approved in the United States in 2000); Fiasp (nearly identical to Novolog, but with added excipients for faster absorption, approved in the United States in 2000); Levemir (analog insulin approved in the United States in 2005); Victoza (Type 2 medicine approved in the United States in 2010); Tresiba (analog insulin approved in the United States in 2015); and Ozempic (Type 2 medicine approved in the United States in 2017).

45. Novo Nordisk makes billions of dollars from these medications. In the United States alone, in 2022, Novo Nordisk made approximately $5.5 billion on Ozempic, $919 million on Victoza, $390 million on Tresiba, $224 million on Levemir, and $230 million on human

[15]Knox, *supra* note 2.

insulins. From 2020 to 2022, Novo Nordisk reported making nearly $24,000,000,000 on diabetes care just in the United States.[16]

46. Novo Nordisk transacts business in Maryland and in Baltimore specifically.

47. Novo Nordisk advertises and distributes informational materials to Maryland and Baltimore physicians as well as directly to consumers in this jurisdiction, targeting the local market for the sale of its diabetes drugs. Novo Nordisk further employs sales representatives to promote and sell the subject diabetes medications manufactured by Novo Nordisk in Baltimore and Maryland.

48. At all relevant times, Novo Nordisk, in furtherance of the Artificial Pricing Scheme, published prices for the subject diabetes medications in Maryland, knowing payments and reimbursements by Baltimore (and others) would be based on these false and inflated list prices.

49. And indeed, during the relevant period, Baltimore did purchase or reimburse for subject diabetes medications manufactured by Novo Nordisk and priced based on the false and inflated list prices Novo Nordisk caused to be published in Maryland in furtherance of the Artificial Pricing Scheme.

2. Eli Lilly

50. Defendant Eli Lilly and Company ("Eli Lilly") is an Indiana corporation with its principal place of business in Indiana.

51. Eli Lilly is registered to do business in Maryland and has been since 1963.

52. Eli Lilly manufactures, promotes, and distributes a number of the subject diabetes medications in Maryland and throughout the United States. These medications include: Humulin

[16] Nordisk Annual Report 2022, https://www.novonordisk.com/content/dam/nncorp/global/en/investors/irmaterial/annual_report/2023/novo-nordisk-annual-report-2022.pdf

N and Humulin R (human insulins approved in the United States in 1982); Humalog (analog insulin approved in the United States in 1996); Trulicity (Type 2 medication approved in the United States in 2014); and Basaglar (analog insulin approved in the United States in 2015).

53. Eli Lilly makes billions from these medications. Within the United States alone, Eli Lilly made approximately $5.6 billion from Trulicity, $730 million from Humulin, $1.19 Billion from Humalog, and $470 million from Basaglar in 2022.[17]

54. Eli Lilly transacts business in Maryland and in Baltimore specifically.

55. Eli Lilly advertises and distributes informational materials to Maryland and Baltimore physicians as well as directly to consumers in this jurisdiction, targeting the local market with its diabetes drugs. Eli Lilly further employs sales representatives to promote and sell the subject medications manufactured by Eli Lilly in Maryland and Baltimore.

56. At all relevant times, Eli Lilly, in furtherance of the Artificial Pricing Scheme, published prices for the subject medications in Maryland knowing payments and reimbursements by Baltimore (and others) would be based on these false and inflated list prices.

57. And indeed, during the relevant period, Baltimore did purchase or reimburse for subject diabetes medications manufactured by Eli Lilly and priced based on the false and inflated list prices Eli Lilly caused to be published in Maryland in furtherance of the Artificial Pricing Scheme.

3. Sanofi

58. Defendant Sanofi-Aventis U.S. LLC ("Sanofi") is a Delaware limited liability company with its principal place of business in New Jersey.

[17]Eli Lilly 2022 Annual Report (Form 10-K) (FYE 12/31/2022)

59. Sanofi manufactures, promotes, and distributes a number of the subject diabetes medications in Maryland and throughout the United States. These medications include: Lantus (an analog insulin approved in the United States in 2000); Apidra (an analog insulin approved in the United States in 2004); Toujeo (an analog insulin approved in the United States in 2015); and Soliqua (a Type 2 medication approved in the United States in 2016).

60. Sanofi makes billions from these medications. Within the United States alone, Sanofi made approximately $808 million on Lantus, $303 million on Toujeo, and $127 million on Soliqua in net sales in 2022.[18]

61. Sanofi transacts business in Maryland and in Baltimore specifically.

62. Sanofi advertises and distributes informational materials to Maryland and Baltimore physicians as well as directly to consumers in this jurisdiction, targeting the local market with its diabetes drugs. Sanofi further employs sales representatives to promote and sell the subject medications manufactured by Sanofi in Maryland and Baltimore.

63. At all relevant times, Sanofi, in furtherance of the Insulin Pricing Scheme, published prices for the subject medications in Maryland knowing payments and reimbursements by Baltimore (and others) would be based on these false and inflated list prices.

64. And indeed, during the relevant period, Baltimore did purchase or reimburse for subject diabetes medications manufactured by Sanofi and priced based on the false and inflated list prices Sanofi caused to be published in Maryland in furtherance of the Artificial Pricing Scheme.

[18]Sanofi 2022 Annual Report (Form 20-F) (FYE 12/31/22), https://www.sanofi.com/assets/dotcom/content-app/publications/annual-report-on-form-20-f/2022-01-01-form-20-f-2022-en.pdf.

C. PBM Defendants

1. Express Scripts

65. "Express Scripts," in this Complaint, refers collectively to Defendants Express Scripts, Inc.; Express Scripts Pharmacy, Inc.; ESI Mail Pharmacy Service, Inc.; Express Scripts Administrators, LLC; Evernorth Health, Inc.; and Medco Health Solutions, Inc., as well as any predecessor and successor entities.

66. **Defendant Evernorth Health, Inc.** ("Evernorth"), which previously operated under the name Express Scripts Holding Company, is a Delaware corporation with its principal place of business in Missouri.

67. Through its CEO, as well as its other executives and employees, Evernorth is directly involved in crafting and overseeing the policies that govern the pharmacy and PBM services, including formulary construction, of its subsidiaries and affiliates. Evernorth's conduct related to the artificial pricing scheme had a direct effect in Maryland and resulted in damage to Baltimore.

68. Evernorth's direct and indirect pharmacy and PBM subsidiaries operate throughout Maryland and engaged in the activities giving rise to this action.

69. Evernorth merged with Cigna in December 2018, consolidating their businesses offering health insurance, PBM services, and mail-order pharmacy services. As a result of this merger, the corporate family of Evernorth controls the entire drug acquisition chain (the health plan/insurer, PBM, and pharmacies) used by the approximately 19.5 million individuals insured by Cigna in the United States.

70. **Defendant Express Scripts, Inc.** is a Delaware corporation with a principal place of business in Missouri.

71. Express Scripts, Inc. is a wholly owned subsidiary of Evernorth and is a parent of pharmacy and PBM subsidiaries operating in Maryland that participated in the Artificial Pricing Scheme and the activities giving rise to this action. Through these subsidiaries, Express Scripts Inc. participated in the Artificial Pricing Scheme that harmed Baltimore.

72. **Defendant Express Scripts Administrators, LLC**, dba Express Scripts (formerly known as Medco Health, LLC), is a Delaware Limited Liability company with a principal place of business in Missouri.

73. Express Scripts Administrators, LLC, is a wholly owned subsidiary of Evernorth and provided PBM services in Maryland that implemented the Artificial Pricing Scheme and participated in the activities giving rise to this action.

74. **Defendant Express Scripts Pharmacy, Inc.** is a Delaware Corporation with a principal place of business in Missouri.

75. Express Scripts Pharmacy, Inc. is a wholly owned subsidiary of Evernorth and provided mail-order pharmacy services in Maryland that implemented the Artificial Pricing Scheme and participated in the activities giving rise to this action.

76. **Defendant ESI Mail Pharmacy Service, Inc.** is a Delaware corporation with its principal place of business in Missouri.

77. ESI Mail Pharmacy Service, Inc. is a wholly owned subsidiary of Evernorth and provided mail-order pharmacy services in Maryland that implemented the Artificial Pricing Scheme and participated in the activities giving rise to this action.

78. **Defendant Medco Health Solutions, Inc.** is a Delaware corporation with its principal place of business in New Jersey, acquired by Express Scripts in 2012.

79. Before its acquisition, Medco Health Solutions, Inc. provided PBM and mail-order pharmacy services in Maryland. Since the merger, the combined company, continued under the name Express Scripts, provides the same services.

80. Through an interlocking web of directors and executives and overlapping corporate structure, Evernorth and Express Scripts, Inc. control Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Medco Health Solutions, Inc., and Express Scripts Pharmacy, Inc.'s business, management, and operations related to those companies' functions relevant to the Artificial Pricing Scheme, namely, operations related to formulary construction, negotiations with drug manufacturers, and mail-order pharmacy services.

a. During the relevant period, Evernorth and its direct and indirect subsidiaries have shared common officers, directors, and executives.

b. Evernorth is a parent company to Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc., and Express Scripts, Inc. and directly or indirectly owns all the stock of these companies.

c. The corporate family of Evernorth does not operate as separate entities but rather operates as a single entity. Indeed, Cigna presents Evernorth and its subsidiaries as operating as a singular "segment" of Cigna's operations that "includes a broad range of coordinated and point solution health services and capabilities" and provides PBM and pharmacy services.[19] The day-to-day operations of this corporate family reflect the public statements, filings, and documents that present the Evernorth corporate family as not operating as separate entities.

[19] The Cigna Group Annual Report (Form 10-K) (FYE 12/31/21).

d. The executives of the various subsidiaries (Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc., and Express Scripts, Inc.) all ultimately report to the executives of Evernorth.

81. Express Scripts is named as a Defendant in its capacities as a PBM and mail-order pharmacy.

82. Express Scripts played a critical role in the Artificial Pricing Scheme and caused harm to Baltimore.

83. Express Scripts offered pharmacy benefit services to Maryland payors, including Baltimore through 2017, and has derived considerable revenue from doing so. In providing these services, Express Scripts made misrepresentations and omitted material information about its services and the Artificial Pricing Scheme and used the false and inflated list prices generated by the Artificial Pricing Scheme in determining the amounts received from payors, including Baltimore.

84. As a mail-order pharmacy network, Express Scripts also purchased the subject diabetes medications to be dispensed in its pharmacies. In this capacity, Express Scripts knowingly profited from the false and inflated list prices set through the Artificial Pricing Scheme by profiting from the difference between the list prices for the subject diabetes medications, minus the rebates and other payments received from the Manufacturer Defendants, and the amounts received from payors, like Baltimore. The amounts received from payors, like Baltimore, were set based on the false and inflated list prices in concert with Express Scripts in its capacity as a PBM.

85. Express Scripts entered agreements with each of the Manufacturer Defendants related to the rebates and other payments made by the Manufacturer Defendants to Express Scripts

as a quid pro quo for favorable formulary designations along with agreements related to selling the subject diabetes medications through Express Scripts pharmacies.

2. CVS

86. "CVS," in this Complaint, refers collectively to Defendants CVS Health Corporation, CVS Pharmacy, Inc., Caremark Rx, LLC, CaremarkPCS Health LLC, and Caremark, LLC, as well as any predecessor and successor entities.

87. **Defendant CVS Health Corporation** ("CVS Health") is a Delaware corporation with a principal place of business in Rhode Island.

88. CVS Health offers comprehensive PBM services in Maryland. Through its CEO, as well as other executives and employees, CVS Health is directly and regularly involved in crafting and overseeing the company policies that govern the pharmacy and PBM services, including formulary construction, of its subsidiaries and affiliates. And CVS Health's conduct related to the Artificial Pricing Scheme had a direct effect in Maryland and resulted in damage to Baltimore.

89. CVS Health acquired Aetna in November 2018, consolidating their businesses offering health insurance, PBM services, and mail-order and retail pharmacy services. As a result of this acquisition, CVS Health controls the entire drug acquisition chain (the health plan/insurer, PBM, and pharmacies) for the millions of individuals in the United States who are insured by Aetna.

90. **Defendant CVS Pharmacy, Inc.** ("CVS Pharmacy") is a Rhode Island corporation with a principal place of business in Rhode Island.

91. CVS Pharmacy is a wholly owned subsidiary of CVS Health that provided pharmacy services in Maryland that implemented the Artificial Pricing Scheme and participated in the activities giving rise to this action.

92. **Defendant Caremark Rx, LLC** is a Delaware limited liability company with a principal place of business in Rhode Island.

93. Caremark Rx, LLC is a subsidiary of CVS Pharmacy. Caremark Rx, LLC, provides PBM and mail-order pharmacy services that implemented the Artificial Pricing Scheme and participated in the activities giving rise to this action.

94. **Defendant CaremarkPCS Health, LLC** is a Delaware limited liability company with a principal place of business in Rhode Island.

95. CaremarkPCS Health, LLC, is an indirect subsidiary of Caremark Rx, LLC. CaremarkPCS Health provides PBM and mail-order pharmacy services that implemented the Artificial Pricing Scheme and participated in the activities giving rise to this action.

96. **Defendant Caremark, LLC,** is a California limited liability company with a principal place of business in Rhode Island.

97. Caremark, LLC, is a subsidiary of Caremark Rx, LLC. Caremark, LLC, provides PBM and mail-order pharmacy services that implemented the Artificial Pricing Scheme and participated in the activities giving rise to this action.

98. Through an interlocking web of directors and executives and overlapping corporate structure, CVS Health, CVS Pharmacy, and Caremark Rx, LLC, control CaremarkPCS Health, LLC and Caremark, LLC's business, management, and operations related to those companies' functions relevant to the Artificial Pricing Scheme, namely, operations related to formulary construction, negotiations with drug manufacturers, and pharmacy services.

a. During the relevant period, CVS Health and its direct and indirect subsidiaries have shared common officers, directors, and executives.

b. CVS Health is the parent company to CVS Pharmacy. CVS Pharmacy is the parent company to Caremark Rx, LLC. Caremark Rx, LLC is, in turn, the parent of Caremark LLC and an indirect parent of CaremarkPCS Health, LLC. At bottom, CVS Health is the direct or indirect parent to all of the CVS Defendants and owns or controls all of the stock or shares in each of these entities either directly or indirectly.

c. The corporate family of CVS Health does not operate as separate entities but rather as a single entity. CVS Health notes that, together with its subsidiaries, it is a "leading diversified health solutions company" offering PBM and pharmacy services.[20] The day-to-day operations of this corporate family reflect the public statements, filings, and documents that present the CVS Health corporate family as not operating as separate entities.

d. The executives of the various subsidiaries (CVS Pharmacy, Caremark Rx, LLC, CaremarkPCS Health, LLC, and Caremark, LLC) all ultimately report to the executives of CVS Health.

99. CVS is named as a Defendant in its capacities as a PBM and pharmacy.

100. CVS played an integral role in the Artificial Pricing Scheme and caused harm to Baltimore.

101. CVS offered pharmacy benefit management services to Maryland payors, including Baltimore beginning in 2018, and has derived considerable revenue from doing so. In

[20]CVS Health Annual Report (Form 10-K) (FYE 12/31/22)

providing these services, CVS made misrepresentations and omitted material information about its services and the Artificial Pricing Scheme and used the false and inflated list prices generated by the Artificial Pricing Scheme in determining the amounts received from payors, including Baltimore.

102. As a mail-order and retail pharmacy network, CVS also purchased the subject diabetes medications to be dispensed in its pharmacies. In this capacity, CVS knowingly profited from the false and inflated list prices set through the Artificial Pricing Scheme by profiting from the difference between the list prices for the subject diabetes medications, minus the rebates and other payments received from the Manufacturer Defendants, and the amounts received from payors, like Baltimore. The amounts received from payors, like Baltimore, were set based on the false and inflated list prices in concert with CVS in its capacity as a PBM.

103. CVS entered agreements with each of the Manufacturer Defendants related to the rebates and other payments made by the Manufacturer Defendants as a quid pro quo for favorable formulary designations along with agreements related to selling the subject diabetes medications through CVS pharmacies.

3. OptumRx

104. "OptumRx," in this Complaint, refers collectively to Defendants UnitedHealth Group, Inc., Optum, Inc., OptumRx, Inc., and OptumInsight, Inc., as well as any predecessor and successor entities.

105. **Defendant UnitedHealth Group, Inc.** ("United Health Group") is a Delaware corporation with its principal place of business in Minnesota.

106. Through its officers, executives, and employees, UnitedHealth Group, Inc. is directly involved in crafting and overseeing the company policies that govern the pharmacy and

PBM services, including formulary construction, of its subsidiaries and affiliates. Accordingly, UnitedHealth Group, Inc. participated in the Artificial Pricing Scheme and the activities giving rise to this action that had a direct effect in Maryland.

107. In addition to providing PBM and mail-order pharmacy services, UnitedHealth Group owns and controls UnitedHealthcare, one of the largest, if not the largest, insurance companies in the United States. As a result, UnitedHealth Group controls the entire drug acquisition chain (the health plan/insurer, PBM, and pharmacies) used by the approximately 41 million individuals insured by UnitedHealthcare in the United States.

108. **Defendant Optum, Inc.** is a Delaware corporation with its principal place of business in Minnesota.

109. Optum, Inc. oversees three businesses: Optum Health, Defendant OptumInsight, Inc., and Defendant OptumRx, Inc. Accordingly, through its officers, executives, and employees, Optum, Inc. is directly involved in crafting and overseeing the company policies that govern the PBM services and formulary construction of its subsidiaries. As such, Optum, Inc. participated in the Artificial Pricing Scheme and the activities giving rise to this action.

110. **Defendant OptumRx, Inc.** is a California corporation with its principal place of business in California.

111. OptumRx, Inc. offers PBM and mail-order pharmacy services throughout the United States, including in Maryland. In providing these services, OptumRx participated in the Artificial Pricing Scheme and the activities giving rise to this action.

112. **Defendant OptumInsight, Inc.** is a Delaware corporation with its principal place of business in Minnesota.

113. OptumInsight, Inc. offers consulting services to companies in the health industry. In this capacity, during the relevant period, OptumInsight, Inc. coordinated with the Manufacturer Defendants in furtherance of the Artificial Pricing Scheme.

114. Through an interlocking web of directors and executives and overlapping corporate structure, UnitedHealth Group and Optum, Inc. control OptumRx, Inc. and OptumInsight, Inc.'s business, management, and operations related to those companies' functions relevant to the Artificial Pricing Scheme, namely, operations related to formulary construction, negotiations with drug manufacturers, mail-order pharmacy services, and healthcare consulting services.

a. During the relevant period, UnitedHealth Group and its direct and indirect subsidiaries have shared common officers, directors, and executives.

b. UnitedHealth Group is the parent of Optum, Inc. Optum, Inc. is the parent to OptumRx Holdings, LLC, which is the parent of OptumRx, Inc. Similarly, Optum, Inc. is the parent to OptumInsight Holdings, LLC, which is the parent to OptumInsight, Inc. Accordingly, UnitedHealth Group either directly or indirectly owns all of the stock or shares in Optum, Inc., OptumRx, Inc., and OptumInsight, Inc.

c. The corporate family of UnitedHealth Group and Optum does not operate as separate entities but rather as a single entity. UnitedHealth Group makes clear that "Optum delivers care aided by technology and data"[21] through its "business units – OptumInsight, OptumHealth and OptumRx" and that the "company's health services businesses [have a] unif[ied] [] market

[21] *Optum: Technology and data-enabled care delivery*, UnitedHealth Group, https://www.unitedhealthgroup.com/people-and-businesses/businesses/optum.html (last visited Feb. 6, 2024);

presence."[22] The day-to-day operations of this corporate family reflect the public statements, filings, and documents that present the UnitedHealth Group and Optum corporate family as not operating as separate entities.

d. The executives of the various subsidiaries (Optum, Inc., OptumRx, Inc., and OptumInsight, Inc.) all ultimately report to the executives of UnitedHealth Group.

115. OptumRx is named as a Defendant in its capacities as a PBM and pharmacy.

116. OptumRx played an integral role in the Artificial Pricing Scheme and caused harm to Baltimore.

117. OptumRx offered pharmacy benefit services to Maryland payors and has derived considerable revenue from doing so. In providing these services, OptumRx made misrepresentations and omitted material information about its services and the Artificial Pricing Scheme and used the false and inflated list prices generated by the Artificial Pricing Scheme in determining the amounts received from payors.

118. As a mail-order pharmacy network, OptumRx also purchased the subject diabetes medications to be dispensed in its pharmacies. In this capacity, OptumRx knowingly profited from the false and inflated list prices set through the Artificial Pricing Scheme by profiting from the difference between the list prices for the subject diabetes medications, minus the rebates and other payments received from the Manufacturer Defendants, and the amounts received from payors, like Baltimore. The amounts received from payors, like Baltimore, were set based on the false and inflated list prices in concert with OptumRx in its capacity as a PBM.

[22] *UnitedHealth Group Announces 'Optum' Master Brand for Its Health Services Businesses*, BusinessWire (Apr. 11, 2011), https://www.businesswire.com/news/home/20110411005701/en/UnitedHealth-Group-Announces-%E2%80%9COptum%E2%80%9D-Master-Brand-for-Its-Health-Services-Businesses.

119. OptumRx entered agreements with each of the Manufacturer Defendants related to the rebates and other payments made by the Manufacturer Defendants as a quid pro quo for favorable formulary designations along with agreements related to selling the subject diabetes medications through OptumRx pharmacies.

III. JURISDICTION AND VENUE

A. Subject Matter Jurisdiction

120. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. § 1331 and 18 U.S.C. § 1964(c) because this action alleges violations of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1962. Further, this Court has supplemental jurisdiction over the Maryland law claims pursuant to 28 U.S.C. § 1367.

B. Personal Jurisdiction and Venue

121. Personal jurisdiction over each Defendant is proper. Each Defendant transacts business in Maryland, maintains substantial contacts in Maryland, and committed the wrongs alleged herein in whole or part within the state and in Baltimore specifically. This action arises out of and relates to Defendants' contacts with this forum.

122. The transactions at issue occurred within Maryland and involved Maryland residents. And the Artificial Pricing Scheme was directed at and had the foreseeable and intended effect of causing injury to persons residing in, located in, or doing business in Maryland.

123. Defendants purposefully availed themselves of the privilege of doing business within Maryland and, therefore, this district. Defendants derived substantial financial gain from their business within this state. Defendants should reasonably have anticipated being brought into this court given their continuous, systematic, and case-related business contacts, including the tortious acts described herein.

124. Defendants submitted themselves to the jurisdiction of this Court by marketing themselves, encouraging the use of their drugs and services, and purposefully cultivating a profitable relationship in Maryland.

125. Each Defendant has systematically served a market in Maryland in relation to the Artificial Pricing Scheme and caused injury in Maryland such that there is a strong relationship among Defendants, this forum, and the litigation.

126. Each Defendant would be subject to the jurisdiction of a court of general jurisdiction in Maryland.

127. Finally, 18 U.S.C. § 1965(b) also grants this Court personal jurisdiction over all Defendants. This is an action under 18 U.S.C. § 1964, and the ends of justice require that all Defendants who participated in the racketeering enterprise be brought before this court in a single action for a single trial.

IV. FACTUAL ALLEGATIONS

A. Diabetes

128. Diabetes is a chronic condition in which the body either does not produce enough insulin (Type 1 diabetes) or cannot effectively use the insulin it produces (Type 2 diabetes).[23] Insulin is an important hormone released by the pancreas into the bloodstream that allows the body's cells to use glucose (sugar) for energy. Without the proper amount of insulin, or if the body is not using the hormone properly, glucose accumulates in the bloodstream, causing hyperglycemia (high blood sugar). Untreated diabetes and the resulting hyperglycemia can cause damage to nerves, blood vessels, tissues, and organs.

[23]Additional, less common, types of diabetes also exist, such as Type 3c diabetes which is caused by non-autoimmune damage to the pancreas.

129. Indeed, without treatment, diabetes and its complications can be fatal. In 2021, Diabetes was the eighth leading cause of death in the United States.[24] In Maryland, it was the seventh leading cause of death.[25] So too in Baltimore.[26]

130. Both nationwide and in Maryland, diabetes is a growing problem. According to a 2021 publication by the American Diabetes Association, around 11.8% of Maryland's adult population has been diagnosed with diabetes while approximately another 3% of the population has undiagnosed diabetes. This number is only growing as 33.7% of the adult population has what is categorized as "prediabetes" (elevated blood glucose levels that have not yet reached the level of diabetes), and an additional 42,623 people are expected to be diagnosed with the condition every year.[27]

131. These numbers are starker in Baltimore. According to U.S. News & World Report, 13% of those in Baltimore are diagnosed with diabetes, a significant increase from the national median of 10.4% and the rate in Maryland as a whole.[28]

132. Diabetes does not affect all populations equally. Diabetes is both more prevalent and more lethal in the African American community. The rate of diabetes among African American men and women is 60% higher than it is among the white population. African American diabetics are twice as likely to die, three times as likely to end up hospitalized, twice as likely to

[24] *See* American Diabetes Association, *Statistics About Diabetes*, (last visited Jan. 25, 2024), https://diabetes.org/about-diabetes/statistics/about-diabetes#:~:text=Deaths,a%20total%20of%20399%2C401%20certificates.

[25] *See* Centers for Disease Control and Prevention, National Center for Health Statistics. National Vital Statistics System, Mortality 2018-2021 on CDC WONDER Online Database, (last visited Jan. 25, 2024), http://wonder.cdc.gov/ucd-icd10-expanded.html.

[26] *See id.*

[27] *See* American Diabetes Association, *The Burden of Diabetes in Maryland* (Oct. 2021), https://www2.diabetes.org/sites/default/files/2021-11/ADV_2021_State_Fact_sheets_Maryland_rev.pdf

[28] U.S. News & World Report, *Overview of Baltimore city, MD*, (last visited Jan 25, 2024), https://www.usnews.com/news/healthiest-communities/maryland/baltimore-city.

undergo leg or foot amputation, and three times more likely to have end-stage kidney disease than their white counterparts.[29]

133. In Baltimore, where more than 60% of the population is African American, these disparities in diabetes rates and outcomes are particularly troubling.

B. Insulin

134. Despite its status as a leading cause of death in the United States, Maryland, and Baltimore, diabetes is a treatable condition and has been since the discovery of insulin in the 1920s. Patients who can afford and follow a treatment plan are able to avoid severe health complications associated with diabetes.

135. Before the discovery of insulin in 1921, diabetes was an inescapably fatal diagnosis. The only treatments that succeeded in "buy[ing] patients a few extra years" were extreme diets.[30] These diets were so severe, however, that they were known to result in death from starvation.

136. But, in 1921, Frederick Banting and Charles Best successfully extracted insulin from the pancreas of a dog and used that insulin to keep another dog with severe diabetes alive. Later, with the help of J.B. Collip and John Macleod, the team developed more refined insulin from the pancreases of cattle and used that insulin to normalize the dangerously high blood glucose levels of a young boy.[31]

137. Since this discovery, Insulin has become an essential medication in the care for Type 1 diabetics and an often used and important treatment for Type 2 diabetics, particularly for those whose disease has progressed.

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[29]Michael Merschel, *The Challenge of Diabetes in the Black Community Needs Comprehensive Solutions*, American Heart Association News (July 13, 2021), https://www.heart.org/en/news/2021/07/13/the-challenge-of-diabetes-in-the-black-community-needs-comprehensive-solutions.

[30]American Diabetes Association, *The History of a Wonderful Thing We Call Insulin*, (July 1, 2019), https://diabetes.org/blog/history-wonderful-thing-we-call-insulin.

[31]*Id.*

138. Banting refused to put his name on the patent to insulin out of a belief that it would be unethical for a doctor to profit from a discovery that would save lives. "Insulin does not belong to me, it belongs to the world," Banting made clear.[32] Instead, Banting's co-inventors famously sold the patent to the University of Toronto for $1 each to try to ensure that the life-saving medication would remain affordable.

139. In turn, the University of Toronto then contracted with Eli Lilly and the precursors of Novo Nordisk to mass-produce insulin, allowing the companies to apply for patents on any of their own advancements.[33]

140. For many years, insulin was derived, like it was at the outset, from animals like cattle and pigs. This animal insulin was, as was the case during the first treatments, effective. Yet animal-derived insulin was far from perfect. Animal-derived insulin was known to cause allergic reactions in many patients.[34] It was also, particularly in its infancy, fairly short-acting, requiring frequent injections.[35] And, as diabetes became more prevalent, there was a concern that the need for insulin would exceed the available supply of animal organs.[36]

141. Since the days of animal-derived insulin, there have been two particularly notable achievements in the production of insulin: the creation of synthetic human insulin followed by the creation of analog insulin.

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[32] Matthew Rozsa, *Insulin used to be affordable – and then, seemingly out of nowhere, it wasn't. Why?*, Salon (Nov. 16, 2022), https://www.salon.com/2022/11/16/insulin-used-to-be-affordable--and-then-seemingly-out-of-nowhere-it-wasnt-why/.

[33]Gary F. Lewis & Patricia L. Brubaker, *The Discovery of Insulin Revisited: Lessons for the Modern Era*, 131 J. Clin. Invest. 1, 6 (Jan. 4, 2021), https://www.jci.org/articles/view/142239/pdf.

[34]*See* American Diabetes Association, *The History of a Wonderful Thing We Call Insulin*, (July 1, 2019), https://diabetes.org/blog/history-wonderful-thing-we-call-insulin.

[35]Jeremy A. Greene & Kevin R. Riggs, *Why Is There No Generic Insulin? Historical Origins of a Modern Problem*, 372 N. Eng. J. Med. 1171, 1172 (2015).

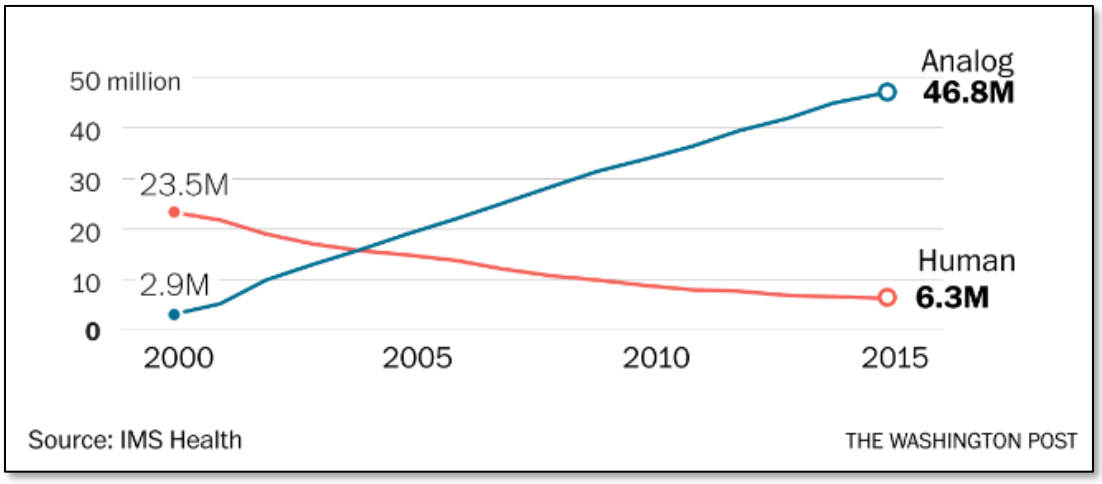
[36]*See* Smithsonian, *Insulin* (last visited Jan. 26, 2024), https://www.si.edu/spotlight/insulin-and-diabetes-management/insulin.

142. In 1982, Eli Lilly began selling synthetic human insulin under the brand name Humulin. This insulin—created by genetically engineering bacteria such as E. coli to produce human insulin—reduced the risk of allergic reactions inherent in using animal-derived insulin. Not long after, Novo and Nordisk developed methods for converting bovine insulin into human insulin and brought their own synthetic human insulin to market.[37]

143. Next came analog insulin. Analog insulin is produced much like human insulin, but rather than simply replicate the insulin naturally produced in the human body, analog insulins have been slightly modified to provide certain benefits, such as more rapid absorption or slower release. Eli Lilly manufactured the first rapid-acting analog insulin, Humalog, in the mid-1990s, followed by Novo Nordisk's Novolog and Sanofi's Apidra.

144. Analog insulins quickly overtook human insulins as the standard prescription for diabetes care, as exhibited in the graph below.[38]

Figure 5 - The Decline of Human Insulin Use



145. Most insulins on the market have been available since the mid-2000s, at the latest, with just a handful of new insulins entering the market nearly a decade ago. Yet even though these

[37] Greene & Riggs, *supra* note 35, at 1172.
[38] Carolyn Y. Johnson, *Why treating diabetes keeps getting more expensive*, Washington Post (Oct. 31, 2016), https://www.washingtonpost.com/news/wonk/wp/2016/10/31/why-insulin-prices-have-kept-rising-for-95-years/.

drugs have been available for 10, 20, or 20-plus years, their costs have skyrocketed, and the same companies have maintained a stranglehold on the market.

146. One reason for the Manufacturer Defendants' continued control over the market is the fact that there have historically been no true generic insulins available. This stems from insulin's categorization as a "biologic" by federal drug laws, which limits the ability of other companies to produce generic versions. Creating "biosimilar" or "follow-on" products is, like the production of a new drug, "tedious, expensive, and resource-intensive."[39]

147. The Manufacturer Defendants have also employed a number of tactics to ensure they retained control over the insulin market.

148. One such tactic is "patent evergreening," where companies patent as "new inventions" minor modifications to old drugs at strategic times in order to extend patent protection. Sanofi, for example, has stacked 74 patents regarding Lantus, allowing for the product to remain under patent for 37 years (nearly double the normal patent protection period).[40]

149. Similarly, the Manufacturer Defendants use what is called "product hopping," which is the introduction of "new" drugs that are essentially the same as existing drugs just with minor tweaks. For example, as Lantus patents began to expire in other parts of the world, Sanofi introduced Toujeo, which is essentially a higher-concentration version of Lantus.[41]

150. Pay-for-Delay is another mechanism through which the Manufacturer Defendants have kept a stranglehold on the insulin market by paying potential manufacturers of generics or competing drugs to agree to stay out of the market occupied by their brand-name drugs. For

[39]David Hirsch & Aruna Muthumanickam, *The Centenary of Inuslin: Celebrating the Past, Analyzing the Present, and Looking Into the Future*, Doctors for America, https://doctorsforamerica.org/the-centenary-of-insulin-celebrating-the-past-analyzing-the-present-and-looking-into-the-future/ (last visited Feb. 13, 2024).
[40]*Id.*
[41]*Id.*

example, in 2015, Eli Lilly and Sanofi reached an agreement in which Eli Lilly agreed to delay selling drugs competitive with Lantus for 15 months in the U.S.[42]

C. Non-insulin Diabetes Medications

151. More recently, other medications have been developed to help with the treatment of Type 2 diabetes. Dubbed GLP-1 medications, these medications function by mimicking the hormone glucagon-like peptide 1, which stimulates the production of insulin and slows digestion, decreasing blood sugar spikes in patients with Type 2 diabetes. Such medications, like Eli Lilly's Trulicity and Novo Nordisk's Ozempic, can be used in conjunction with insulin to control Type 2 diabetes. Indeed, Sanofi manufactures a combination GLP-1 and insulin called Soliqua.

152. The following chart shows the subject diabetes medications manufactured by the Manufacturer Defendants.

[42]Ronald C. Feldman & Prianka Misra, *The Fatal Attraction of Pay for Delay*, 18 Chi.-Kent J. Intell. Prop. 249, 276 (2019).

Figure 6 - Subject Diabetes Medications

Insulin Type	Action	Name	Company	Approval	Price
Human	Rapid-Acting	Humulin R	Eli Lilly	1982	$164 per vial
		Humulin R 500	Eli Lilly	1982	$1808 per vial $735 per two pen carton
		Novolin R	Novo Nordisk	1991	$165 per vial $320 per 5 pen carton
	Intermediate	Humulin N	Eli Lilly	1982	$170 per vial $673 per 5 pen carton
		Humulin 70/30	Eli Lilly	1989	$162 per vial $531 per 5 pen carton
		Novolin N	Novo Nordisk	1991	$161 per vial $327 per 5 pen carton
		Novolin 70/30	Novo Nordisk	1991	$175 per vial $372 per 5 pen carton
Analog	Rapid-Acting	Humalog	Eli Lilly	1996	$325 per vial $689 per 5 pen carton
		Novolog	Novo Nordisk	2000	$400 per vial $720 per 5 pen carton
		Fiasp	Novo Nordisk	2000	$357 per vial $662 per 5 pen carton
		Apidra	Sanofi	2004	$289 per vial $639 per 5 pen carton
	Long-Acting	Lantus	Sanofi	2000	$307 per vial $550 per 5 pen carton
		Levemir	Novo Nordisk	2005	$322 per vial $554 per 5 pen carton
		Basaglar	Eli Lilly	2015	$389 per 5 pen carton
		Toujeo	Sanofi	2015	$522 per 3 pen carton
		Tresiba	Novo Nordisk	2015	$403 per vial $695 per 5 pen carton
Type 2 Medications		Victoza	Novo Nordisk	2010	$1337 per 3 pen carton
		Trulicity	Eli Lilly	2014	$1114 per 4 pen carton
		Ozempic	Novo Nordisk	2017	$1137 per pen
		Soliqua	Sanofi	2016	$1069 per 5 pen carton

D. Skyrocketing and Coordinated Rises in the Costs of Insulin

153. Across the country, as well as in Maryland, the market for diabetes medications is massive. Over 37 million individuals in the United States have diabetes. The estimated direct medical costs attributable to diabetes is more than $306 billion. Care for those diagnosed with diabetes accounts for 1 in 4 dollars spent on healthcare in the United States.[43]

[43] Parker et al., *Economic Costs of Diabetes in the U.S. in 2022*, 47 Diabetes Care 26, 26 (Jan. 2024), https://diabetesjournals.org/care/article/47/1/26/153797/Economic-Costs-of-Diabetes-in-the-U-S-in-2022.

154. This market of diabetics, many of whom need insulin to survive, is held captive by the Manufacturer Defendants who, as discussed above, control more than 90% of the global insulin market.

155. The Manufacturer Defendants have plentiful opportunities for contact and communication with each other. Each Manufacturer Defendant is a member of the Pharmaceutical Research and Manufacturers of America ("PhRMA"). And each Manufacturer Defendant does communicate with the others through PhRMA. Paul Hudson, the CEO of Sanofi, Douglas J. Langa, EVP of North America Operations and President of Novo Nordisk, and David Ricks, Chair and CEO of Eli Lilly, are on PhRMA's board of directors.

156. This control of the market and opportunity for private coordination have allowed the Manufacture Defendants, as part of the Artificial Pricing Scheme described in depth below, to drive the price of insulin to astronomical levels in lockstep.

157. The increase in the costs of diabetes drugs over the past two decades plus is extreme and "inexplicabl[e]."[44]

158. A single vial of Eli Lilly's Humalog, for example, cost $21 in 1999. By 2019, the price had increased more than tenfold to $332.

159. Similarly, in 2001, a vial of Novo Nordisk's Novolog was just $39.75. In July 2016, that same vial had a list price of $255.40. And by 2021, the list price was $290, up approximately 630%.

160. Lantus, manufactured by Sanofi, cost just $34.81 per vial in 2001. By 2014, it was up to $248.51, a 600% increase. In 2023, it cost $292.07, up nearly 740%.

[44]S. Vincent Rajkumar, MD, *The High Cost of Insulin in the United States: An Urgent Call to Action*, 95 Mayo Clin. Proc. 22, 22 (Jan. 2020).

161. Levemir, manufactured by Novo Nordisk, was just $66.96 when it hit the market in 2006. In 2016, it was up to around $269. By 2019, it was up to $308.14 per vial, a 360% increase from its price just 13 years before.

162. These price hikes are emblematic of the Manufacturer Defendants' pricing practices across the subject diabetes medications.

163. And these prices are rising despite the products themselves staying the same. As one doctor explained: "We're not even talking about rising prices for better products here . . . . I want to make it clear that we're talking about rising prices for the same product . . . there's nothing that's changed about Humalog. It's the same insulin that's just gone up in price and now cost ten times more."[45]

164. Nor can the price hikes be attributed to rising manufacturing costs. Manufacturing costs for insulin remain low—about $10 per vial.

165. The extreme nature of insulin pricing in the United States is made even more clear by looking to the costs of the drug in other countries.

166. In a 2020 study done for the Department of Health and Human Services, RAND found a stark difference between the average price for insulin in the U.S. as compared to 32 other countries. Across all types of insulin, the average price in America was more than ***10 times higher*** than the average for the other countries. Looking just to rapid-acting insulin, the average price in America was nearly ***15 times greater*** than the average price in the other countries.[46]

167. The same is true for the Type 2 medications. Novo Nordisk's Ozempic, for example, costs five times more in the United States than it does in Japan and more than ten times

[45]Natalie Shure, *The Insulin Racket*, American Prospect (June 24, 2019), https://prospect.org/health/insulin-racket/ (second alteration in original).
[46]Doug Irving, *The Astronomical Price of Insulin Hurts American Families*, RAND (Jan. 6, 2021), https://www.rand.org/pubs/articles/2021/the-astronomical-price-of-insulin-hurts-american-families.html.

the price in France. Wegovy and Mounjaro also have radically inflated prices in the United States as compared to other countries.[47]

168. Indeed, while the United States accounts for just 15% of the global insulin market in terms of users, it nevertheless generates nearly 50% of the insulin revenue of pharmaceutical companies.[48]

169. Beyond being extreme, the increases in the prices for the subject diabetes drugs have been coordinated and in lockstep.

170. Manufacturer Defendants have consistently raised their prices in lockstep "within days or even hours" of each other.[49]

171. As described in a Senate Finance Committee Report on the rising costs of insulin (the "Grassley & Wyden Report"), the price matching between the Manufacturer Defendants has been precise and expedient. For example, in one instance, just hours after Sanofi raised the price of Lantus by 16.1% per vial and 9.9% per pen, Novo Nordisk did the same, raising the price of Levemir vials by 16.1% and pens by 9.9%.[50] This pattern repeated time after time. On another occasion, when Sanofi increased the list prices of Levemir vials and pens by 11.9%, Novo Nordisk approved a request to match that 11.9% increase within a day.[51]

172. The below graphs emphasize the coordinated price increases by Eli Lilly and Novo Nordisk in relation to Humalog and Novolog prices and Sanofi and Novo Nordisk in relation to Lantus and Levemir prices.[52]

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[47]Annika Kim Constantino, *Weight-loss drugs are priced substantially higher in the U.S. than in other countries, analysis says*, CNBC (Aug. 17, 2023), https://www.cnbc.com/2023/08/17/weight-loss-drugs-cost-more-in-us-kff-says.html#:~:text=Ozempic%20is%20priced%20at%20%24103,is%20just%20%24328%20in%20Germany.
[48]Julie Belluz, *The absurdly high cost of insulin, explained*, Vox (Nov. 7, 2019), https://www.vox.com/2019/4/3/18293950/why-is-insulin-so-expensive.
[49]Grassley & Wyden Report, *supra* note 10 at 6.
[50]*Id.* at 54.
[51]*Id.* at 56.
[52]Oversight Report, *supra* note 12 at 139.

Figure 7 - Insulin Price Increases: Humalog vs. NovoLog

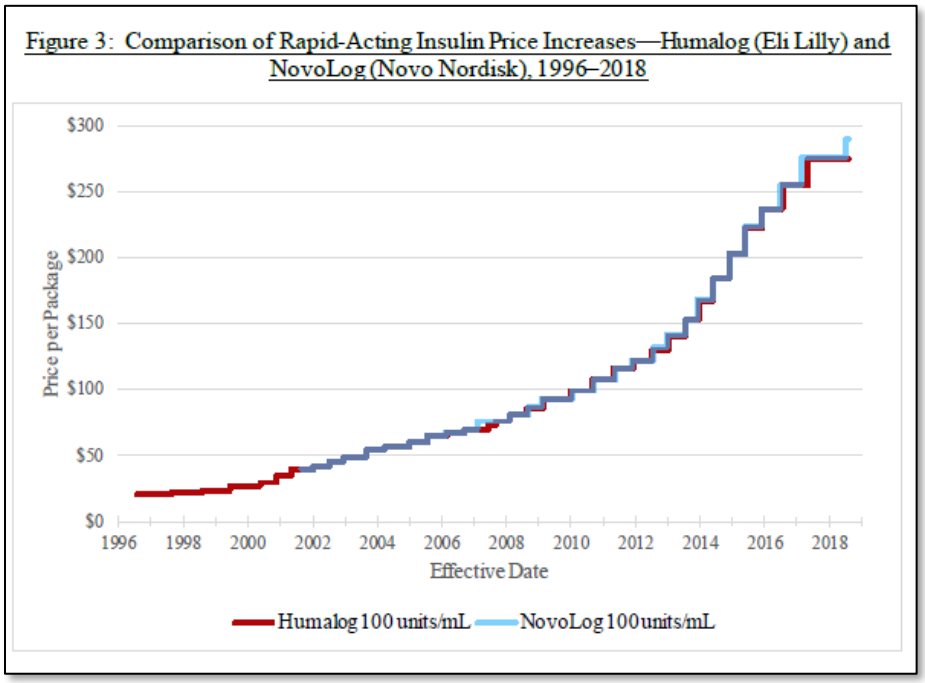
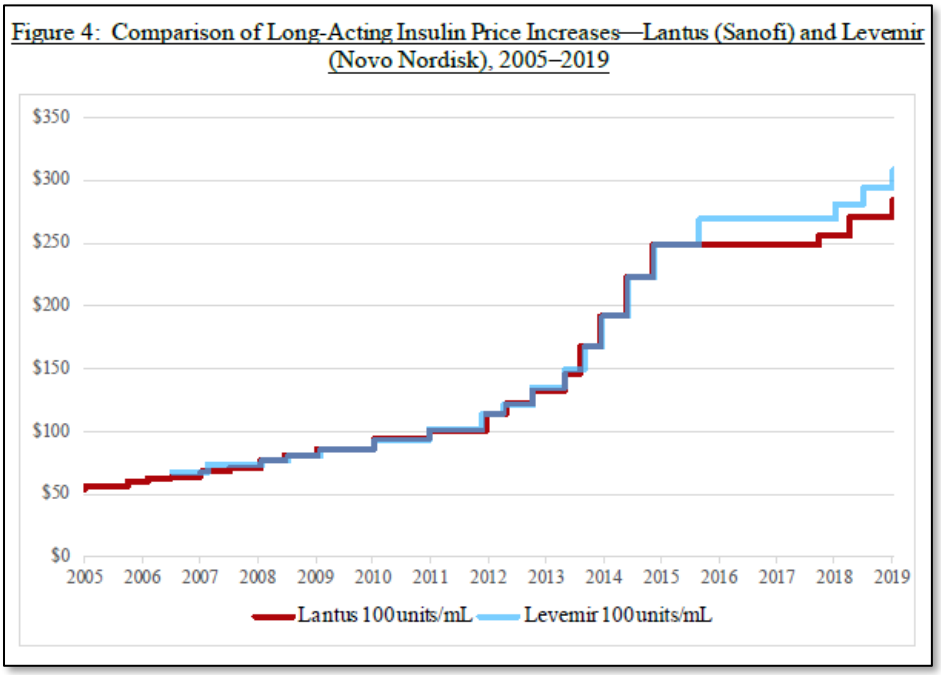
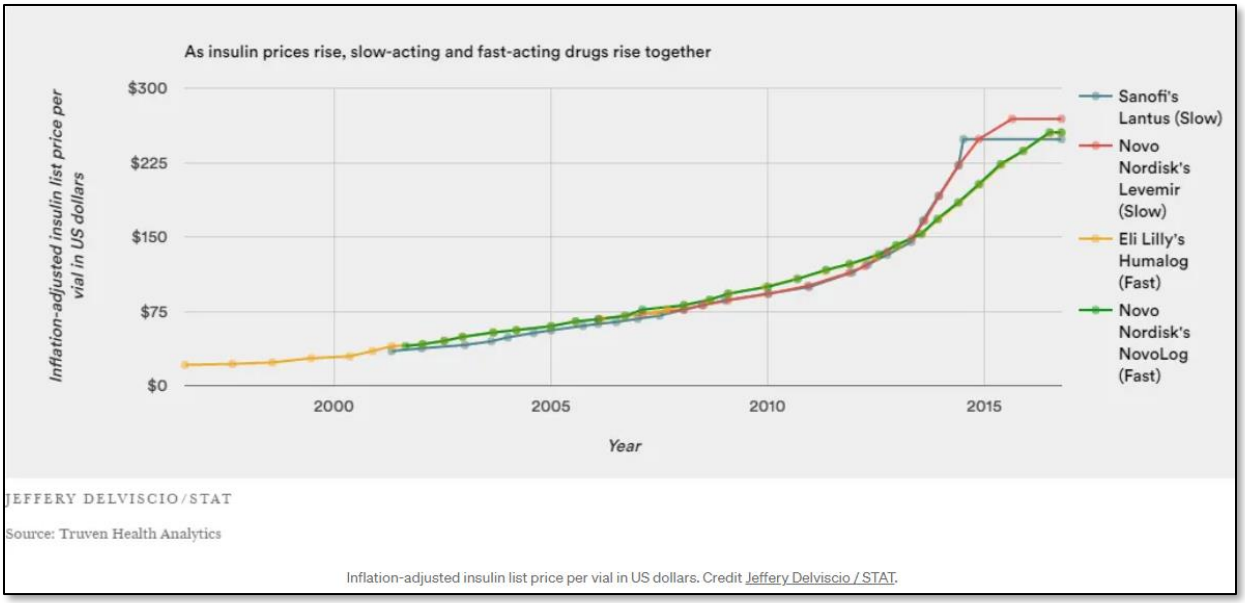


Figure 8 - Insulin Price Increases: Lantus vs. Levemir



173. The following graph further shows how the prices of those same four drugs increased closely and in tandem.[53]

Figure 9 - Insulin Price Increases: Lantus, Levemir, Humalog, and NovoLog



174. The pervasive price hikes and parallel pricing demonstrate the lack of true competition between Manufacturer Defendants and cannot be explained by any legitimate justification.

175. Manufacturers have attempted to justify the extreme price hikes by claiming they are related to research and development costs. For example, as noted by the House Oversight Committee, "Eli Lilly has taken the public position that it prices its products according to each drug's value to the health care system and the need to fund innovation," and in a presentation made by the CEO at a 2017 Healthcare Summit on pricing, there was an emphasis placed on the research and development costs for insulin.[54]

[53]The Intrepid Reporter, *Why does insulin cost so much in America?*, Medium (Mar. 2, 2017), https://medium.com/insulin-report/why-does-insulin-cost-so-much-in-america-4e6b2f598596
[54]Oversight Report, *supra* note 12 at 169.

176. This explanation fails to hold water. Of course, the lockstep nature of the price increases has nothing to do with research and development costs. And both the Grassley & Wyden Report and the House Oversight Committee in its own report on rising drug costs have rejected such explanations for the rising costs of insulin.[55]

177. Indeed, as the House Oversight Committee report explains, Eli Lilly's reported R&D costs related to Humalog between 2005 and 2018 are the equivalent of just 3.6% of the net sales revenue for the drug in the U.S. alone and are dwarfed by global sales, which were 4600% greater than the R&D expenses. So too for Sanofi, which spent just the equivalent of 2.4% of the U.S. net sales for Lantus on R&D for the drug from 1990 to 2018 and announced in 2019 that it was discontinuing research on diabetes medications.[56]

178. This makes sense, given the initial research regarding insulin occurred more than 100 years ago and more recent major developments in insulin—the creation of human and analog insulins —were developed with costs that were incurred decades ago and have since been recouped many times over.

E. PBMs: The Powerful Heart of the Pharmaceutical Supply Chain

179. PBMs play a powerful role in the pharmaceutical supply chain, and the PBM market is, like the market for manufacturing diabetes drugs, highly concentrated. The PBM Defendants—CVS, Express Scripts, and OptumRx—control approximately 80% of the U.S. PBM market and, accordingly, have outsized control over the cost of pharmaceuticals. This is particularly true for the subject diabetes medications where both the manufacturers and PBMs have a stranglehold on their relevant markets.

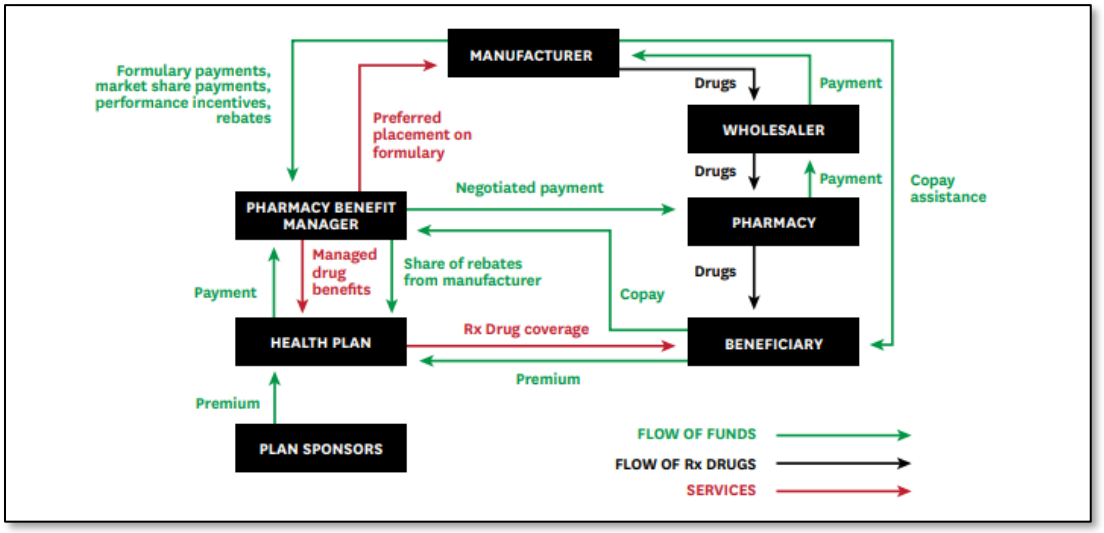
[55]Grassley & Wyden Report, *supra* note 10 at 17; *see* Oversight Report, *supra* note 52 at 164.
[56]Oversight Report, *supra* note 12 at 169-72.

180. The general flow of drugs in the pharmaceutical supply chain is simple. Typically, manufacturers produce the drugs then transfer them to wholesalers. Wholesalers then sell the drugs to pharmacies or other large medical facilities (though in some cases pharmacies buy drugs directly from manufacturers). And pharmacies then provide the drugs to consumers.

181. The flow of money in the pharmaceutical supply chain is more complex as different entities pay different prices for the same drugs due to negotiations done by actors such as PBMs. That said, all prices, at bottom, are based on the prices set by manufacturers, the list price or WAC.

182. As shown in the figure below, PBMs play a central role in setting the prices paid by payors, health plan sponsors, and beneficiaries.[57]

Figure 10 - Model of the Pharmaceutical Supply Chain



183. PBMs, in essence, administer prescription drug benefits for their client health insurers. This entails multiple responsibilities. PBMs perform administrative functions related to insurers' drug benefits, primarily processing pharmacy claims. PBMs also help shape the extent of insurers' coverage, most notably by establishing their drug formularies. These formularies

[57]Neeraj Sood et al., *The Flow of Money Through the Pharmaceutical Distribution System*, USC Schaeffer Center White Paper Series (June 2017), https://healthpolicy.usc.edu/wp-content/uploads/2017/06/The-Flow-of-Money-Through-the-Pharmaceutical-Distribution-System_Final_Spreadsheet.pdf.

determine which drugs are covered (or excluded from coverage) and the amount of drug prices borne by payors and beneficiaries, whether that be a flat copayment amount or a coinsurance percentage. PBMs also establish pharmacy networks, negotiating with pharmacies to provide discounts on the costs associated with filling prescriptions in exchange for access to a broader customer base: the insurers' beneficiaries. Many PBMs, particularly as the industry has become more vertically integrated, also offer their own pharmacies (largely mail-order and specialty pharmacies).

184. The most important role filled by PBMs, however, particularly as it relates to this action, is that of negotiating prices with drug manufacturers. PBMs are generally tasked with negotiating better drug costs for their client by leveraging the power of their market share and role in establishing formularies. Through these negotiations, PBMs enter contracts with drug manufacturers providing for rebates, fees, and other concessions.

185. Since their development in the 1960s, PBMs have become an increasingly ubiquitous aspect of the pharmaceutical supply chain. Today, PBMs administer prescription drug plans for more than 275 million Americans—around 83% of the U.S. population.[58]

186. As discussed above, around 80% of the PBM market in the U.S. is controlled by CVS (33%), Express Scripts (24%), and OptumRx (22%). The next strongest competitor has just 8% market share.[59]

187. Given this market share and corresponding control over the prescription drug plans of hundreds of millions of Americans through their role in establishing formularies, PBMs have enormous power in their dealings with drug manufacturers. Excluding drugs from their

[58] *About PCMA*, PCMA, https://www.pcmanet.org/about/ (last visited Feb. 5, 2024).
[59] Adam J. Fein, *The Top Pharmacy Benefit Managers of 2022: Market Share and Trends for the Biggest Companies*, Drug Channels (May 23, 2023), https://www.drugchannels.net/2023/05/the-top-pharmacy-benefit-managers-of.html

formularies can make those drugs inaccessible to the beneficiaries falling under their controlled plans and therefore crater those drugs' sales. Changing how drugs are treated on their formularies, such as by raising the price for beneficiaries or requiring prior authorization, can similarly cause large reductions in the demand for those drugs where alternatives are made available.

188. PBMs benefit from close relationships, negotiations, and communications between themselves and Manufacturers. This applies doubly when it comes to the Artificial Pricing Scheme.

189. The PBM Defendants are members of the Pharmaceutical Care Management Association ("PCMA"), which is the national association representing PBMs in the United States. Representatives from each PBM Defendant are on the board of directors of PCMA, including David Joyner, EVP of CVS Health and President of CVS Caremark, Patrick Conway, CEO of OptumRx, and Adam Kautzner, President of Express Scripts.

190. PCMA provides the PBM Defendants with routine access to the Manufacturer Defendants as well. The Manufacturer Defendants all sponsor the organization.[60] And the organization's annual meeting bills itself for "senior executives from PBMs and their affiliated business partners – most notable [sic] drug manufacturers" with "private reception rooms" and "excellent opportunities for interactions between PBM members, drug manufacturers, and other industry partners."[61]

191. This meeting, and others like it, provide the Defendants with the opportunity to plan and discuss the details of the Artificial Pricing Scheme in secret.

192. Indeed, lock-step price increases have taken place shortly after PCMA meetings.

[60] *PCMA Sponsors*, PCMA, https://www.pcmanet.org/about/pcma-sponsors/ (last visited Feb. 6, 2024).
[61] *Annual Meeting 2023*, PCMA, https://www.pcmanet.org/pcma-event/annual-meeting-2023/ (last visited Feb. 6, 2024).

193. In 2017, for example, PCMA held its annual meeting on September 25 and 26. Just five days after the conference, on October 1, 2017, Sanofi increased the list price of Lantus by 3% and the list price of Toujeo by 5.4%. Before the end of October, Novo Nordisk decided to implement its own 4% price increase, following Sanofi.[62]

F. The Artificial Pricing Scheme

194. As detailed above, the prices of diabetes medications have skyrocketed, in lockstep, over the past two decades. The Artificial Pricing Scheme is the cause. Defendants, the three PBMs representing control of 80% of the PBM market (CVS, Express Scripts, and OptumRx), and the three manufacturers of diabetes medications with over 90% market share (Eli Lilly, Novo Nordisk, and Sanofi) have worked together through coordinated unfair and deceptive conduct to inflate the price of insulin and other diabetes drugs.

195. For its perniciousness, the scheme is straightforward. The PBM Defendants exchange favorable treatment on their formularies for Manufacturer Defendants raising the list prices of the subject diabetes medications and granting the PBM Defendants increased rebates and other payments. This represents a complete contradiction of the PBM Defendants' assurances they negotiate to save prices for payors and beneficiaries. And, accordingly, Defendants have colluded to prevent the discovery of the Artificial Pricing Scheme.

196. As a direct and proximate result of the Artificial Pricing Scheme, the prices of diabetes medications have increased and purchasers of these medications, whether they be beneficiaries, the uninsured, or payors like Baltimore, have been harmed by drastically overpaying for the subject diabetes medications.

[62] *See Annual Meeting 2017*, PCMA, https://www.pcmanet.org/events/past-events/annual-meeting-2017/ (last visited Feb. 14, 2024); Grassley & Wyden Report, *supra* note 10 at 59.

1. Increased Rebates and Fees

197. The coordinated and astronomical rise in the list price of the subject diabetes medications, discussed above, only demonstrates half of the story. The largely hidden gap between the Manufacturer Defendants' list prices and the net prices they receive after accounting for rebates and other payments made to PBMs is another important aspect of the Artificial Pricing Scheme.

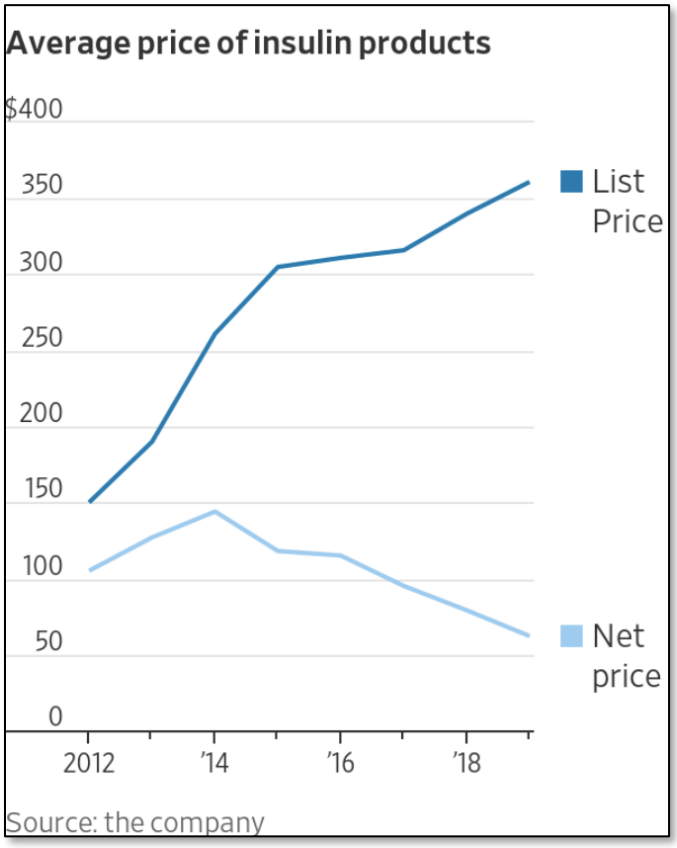
198. This disparity between list and net price is problematic on multiple fronts. As an initial matter, the Manufacturer Defendants know that their public list prices are false and inflated, completely untethered to the net price they receive and the drugs' actual values. They also know that these prices are used as the basis for calculating payments by payors, like Baltimore, and beneficiaries with plans requiring coinsurance. Further, this disparity also demonstrates that PBMs' negotiations regarding the subject diabetes medications are done to favor PBMs, not payors and beneficiaries, despite the PBMs' repeated promises to the contrary.

199. In essence, rather than compete by lowering prices, as would be the case in a fair market. Manufacturer Defendants gain PBMs' approval by raising list prices (which allows PBMs greater profit on the fees they charge that are based on percentage of list prices) and by providing rebates and other payments to PBMs. This is why, while list prices of diabetes medications have skyrocketed, the net price realized by the Manufacturer defendants has remained stable, or even slightly decreased.

200. In the face of public pressure and lawsuits, Manufacturers have, in recent years, noted the disparities between list and net costs—though without revealing their relation to the Artificial Pricing Scheme.

201. Sanofi, for example, has explained that despite the astronomical list price hikes of their insulin drugs, their net prices on those insulins have fallen.[63] The following chart demonstrates the growing disparity between net and list prices, based on data Sanofi provided to the Wall Street Journal.[64]

Figure 11 – Sanofi Insulin Pricing: List Price vs. Net Price I



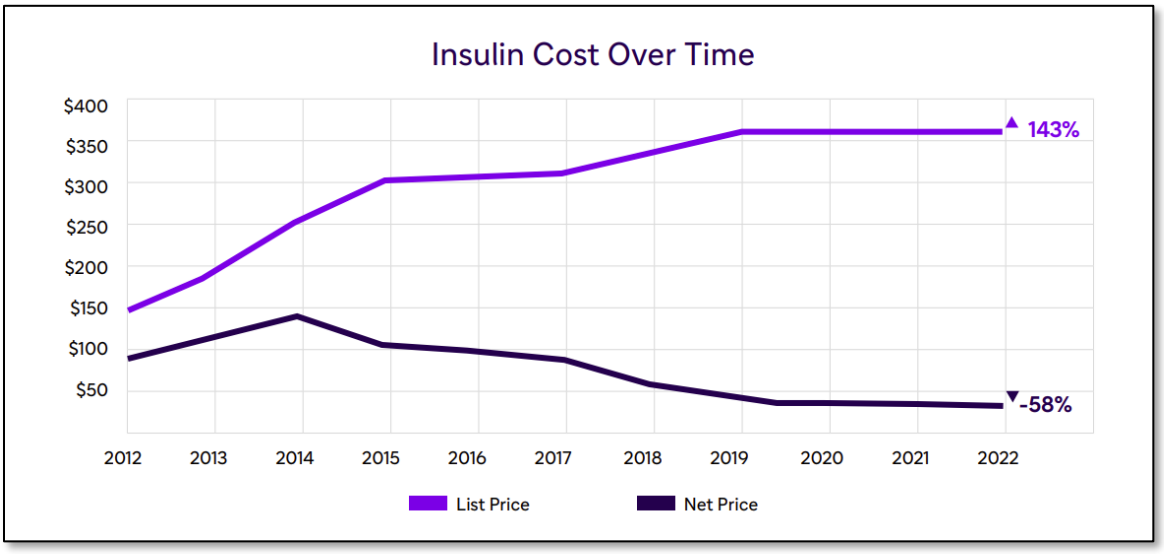
202. Sanofi provided a similar chart in its 2023 Pricing Principles Report.[65]

[63] Eric Sagonowsky, *Net prices for insulins keep dropping, but patients are paying more, Sanofi says*, Fierce Pharma (Mar. 5, 2020), https://www.fiercepharma.com/pharma/net-prices-for-insulins-keep-dropping-but-are-patients-paying-more-sanofi-says

[64] Denise Roland, *Sanofi, Fighting Back in Inulin Price Debate, Says Its Net Prices Fell 11%*, Wall Street Journal (Mar. 4, 2020), https://www.wsj.com/articles/sanofi-fighting-back-in-insulin-price-debate-says-its-net-prices-fell-11-11583340721.

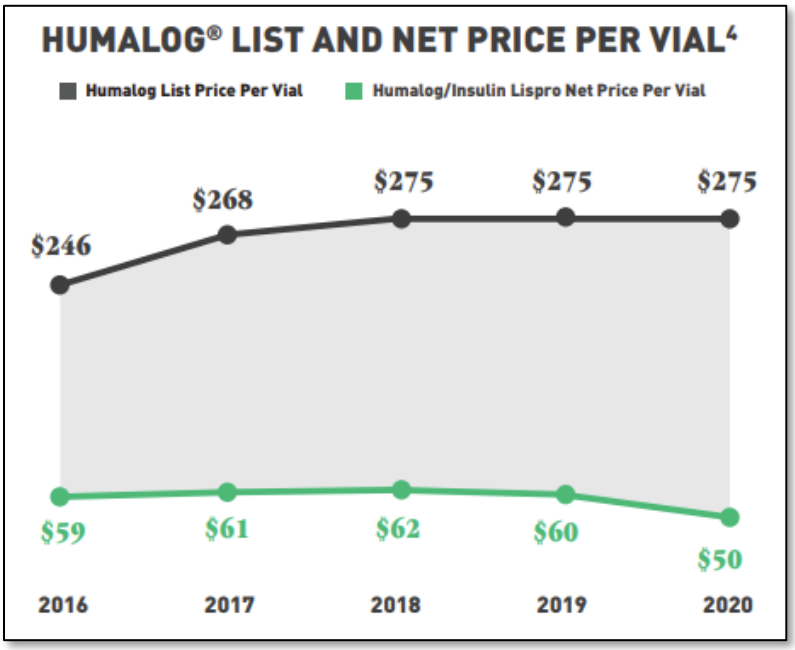
[65] *2023 Pricing Principles Report*, Sanofi (2023), https://www.sanofi.us/dam/jcr:12ad1f3e-aa6a-4f4c-a51b-60adef4a9bb5/Sanofi%202023%20Pricing%20Principles%20Report.pdf (last visited Feb. 6, 2024)

Figure 12 - Sanofi Insulin Pricing: List Price vs. Net Price II



203. Eli Lilly too has highlighted the gap between list and net pricing for their drugs, like Humalog.[66]

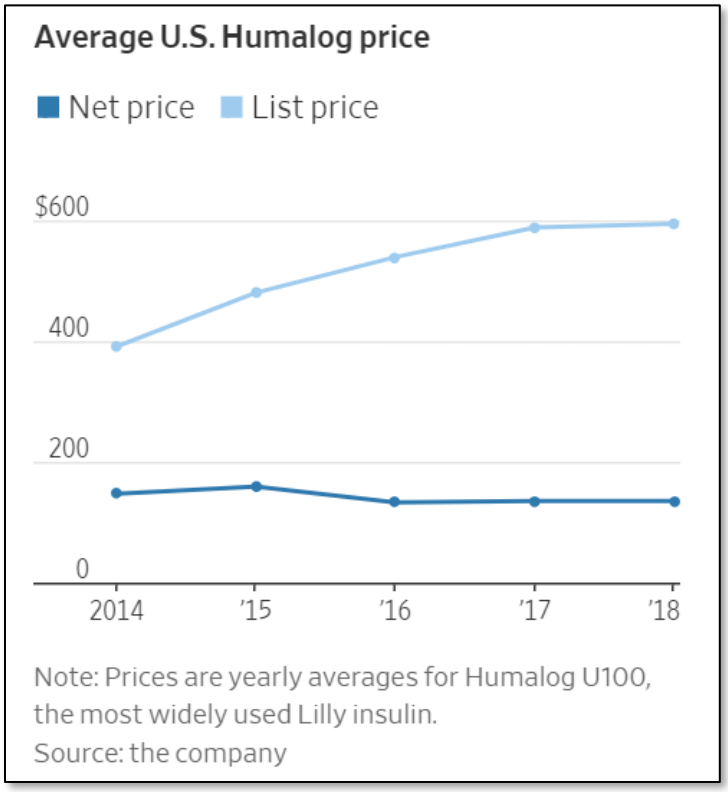
Figure 13 - Eli Lilly Humalog List Price vs. Net Price I



[66] *U.S. Transparency & Affordability*, Eli Lilly and Company (2020), https://assets.ctfassets.net/srys4ukjcerm/1DrEsTfi0aLsCcUOLYEwIT/3ded82590b7d50e81d51a84ca2000a83/2020-ISR-Social-Impact-Transparency-and-Affordability.pdf (last visited Feb. 6, 2024),

204. And Eli Lilly also provided data to the Wall Street Journal to the same effect.[67]

Figure 14 - Eli Lilly Humalog List Price vs. Net Price II

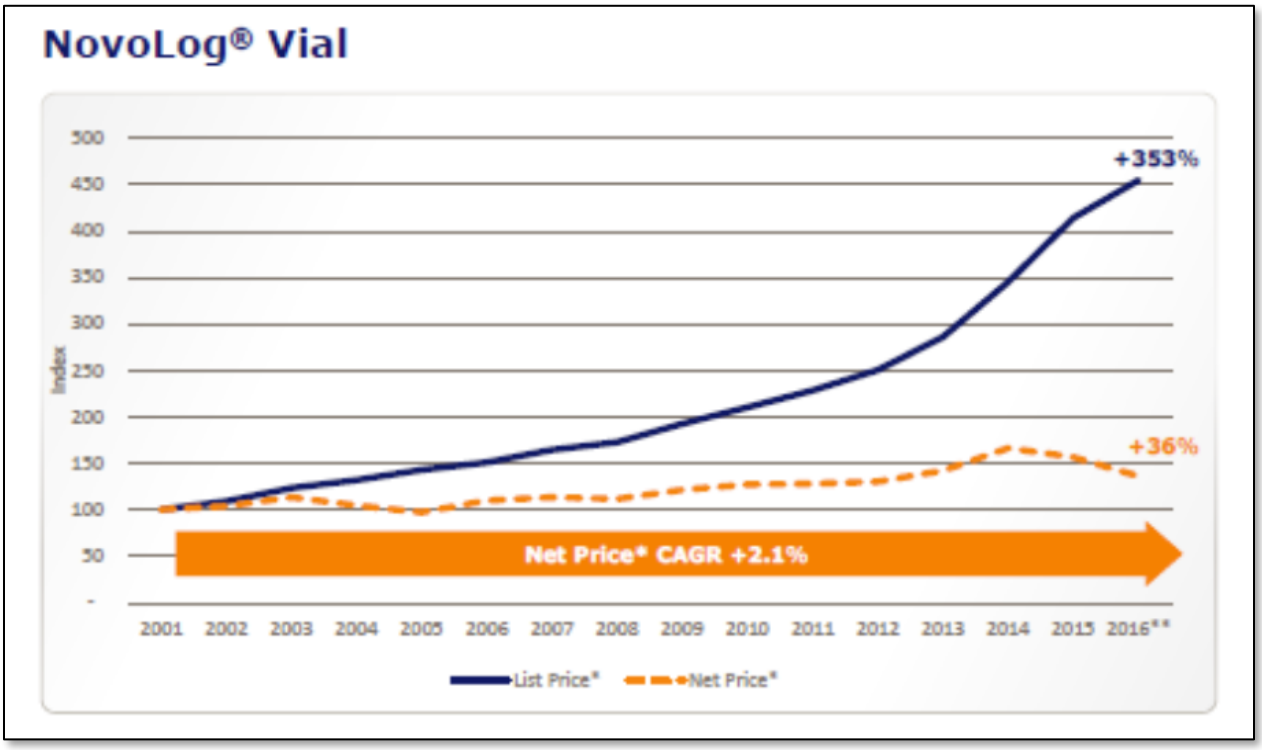


205. Novo Nordisk has done the same, producing charts showing the differences between list and net prices for NovoLog, for example.[68]

[67] Peter Loftus, *As Political Scrutiny Mounts, Eli Lilly Divulges New Insulin Pricing Data*, Wall Street Journal, (Mar. 24, 2019), https://www.wsj.com/articles/as-political-scrutiny-mounts-eli-lilly-divulges-new-insulin-pricing-data-11553436000.

[68] Lisa LaMotta, *Novo Nordisk becomes latest pharma to criticize pricing system*, BiopharmaDive (Dec. 7, 2016), https://www.biopharmadive.com/news/novo-nordisk-diabetes-drug-pricing/431883/.

Figure 15 - Novo Nordisk NovoLog List Price vs. Net Price



206. These growing disparities between the ever-skyrocketing list prices of diabetes medications and the net prices for those drugs stems from the increased rebates and other payments paid to the PBM Defendants in exchange for favorable formulary treatment.

207. These rebates and other payments received from manufacturers have become one of the primary sources of PBM profits, despite the fact that they also receive payment from health plan clients related to claim processing and other administrative responsibilities.

208. PBM Defendants should be using the power of their network and formularies to lower the costs of drugs for their customers. Indeed, that is precisely what the PBM Defendants promise.

209. CVS claims that its PBM services "play[] a critical role in the health care system by negotiating low net costs for our customers" and "help lower overall health care costs."[69]

210. Express Scripts touts that its PBM services "negotiate better prices for your plan" which results in "greater affordability" and "lower pharmacy costs."[70]

211. OptumRx similarly states that it is "[h]elping to lower pharmacy benefit costs" and "pharmacy savings for everyone"; that its goal is to "help plan sponsors and employees . . . lower overall costs"; and that customers can expect the "[l]owest net cost drug procurement and pharmaceutical manufacturer negotiations."[71]

212. The PBM defendants have also repeatedly and explicitly disavowed any role in the rising cost of drugs.

a. On February 9, 2017, Larry Merlo, the President and CEO of CVS Health, stated, "Any suggestion that PBMs are causing prices to rise is simply erroneous."[72]

b. Six days later, on a February 15, 2017, earnings call, Tim Wentworth, the CEO of Express Scripts, claimed that "Drugmakers set prices, and we exist to bring those prices down."[73]

c. On April 10, 2019, executives from each of the PBM Defendants (Amy Bricker, from Express Scripts; Sumit Dutta, from OptumRx; and Thomas

[69] *Pharmacy benefit manager*, CVS Health, https://www.cvshealth.com/services/prescription-drug-coverage/pharmacy-benefits-management.html (last visited Feb. 6, 2024)
[70] *Express Scripts PBM*, Evernorth Health Services, https://www.evernorth.com/our-solutions/express-scripts-pbm (last visited Feb. 6, 2024).
[71] *Pharmacy benefit management (PBM)*, Optum, https://www.optum.com/en/business/employers/pharmacy-care-services.html (last visited Feb. 6, 2024).
[72] Lynn R. Webster, *Who is to blame for skyrocketing drug prices?*, The Hill (Jun. 27, 2017), https://thehill.com/blogs/pundits-blog/healthcare/344115-who-is-to-blame-for-skyrocketing-drug-prices/#:~:text=According%20to%20Bloomberg%2C%20%E2%80%9CPBMs%20deny,15%20earnings%20call.
[73] *Id.*

Moriarty, from CVS) testified before Congress that PBMs were not responsible for the rising prices of insulin.[74]

(1) Mr. Moriarty testified that he couldn't answer why list prices were so high but that he did not think it was because of rebates.

(2) Ms. Bricker testified, "I have no idea why list prices are high and it's not a result of rebates."

(3) Mr. Dutta testified that "we can't see a correlation just when rebates raise list prices."

213. But these representations are false. Both the Manufacturer Defendants and PBM Defendants have realized that they both win by raising list prices in the system of perverse incentives part and parcel of the Artificial Pricing Scheme. By raising list prices, Manufacturer Defendants are able to avoid, or minimize, decreases in profits while continuing to provide PBM Defendants the increasingly high rebates and other payments they demand for favorable treatment on their formularies that act as the gatekeeper to millions of potential customers. And as list prices go up, so do the rebates and other payments from the Manufacturers as well as fees from insurers tied to list prices, and, accordingly, the PBM Defendants' bottom line.

214. As a report regarding PBMs' role in increasing costs commissioned by the Community Oncology Alliance noted:

> While rebates are intended to lower the "net price" of drugs, thereby reducing costs to plan sponsors (including employers), there are several important ways that PBM rebates increase the costs of drugs for both plan sponsors and patients.
>
> … PBMs employ exceedingly vague and ambiguous contractual terms to recast monies received from manufacturers outside the traditional definition of rebates, which in most cases must be shared with plan sponsors. Rebate administration fees,

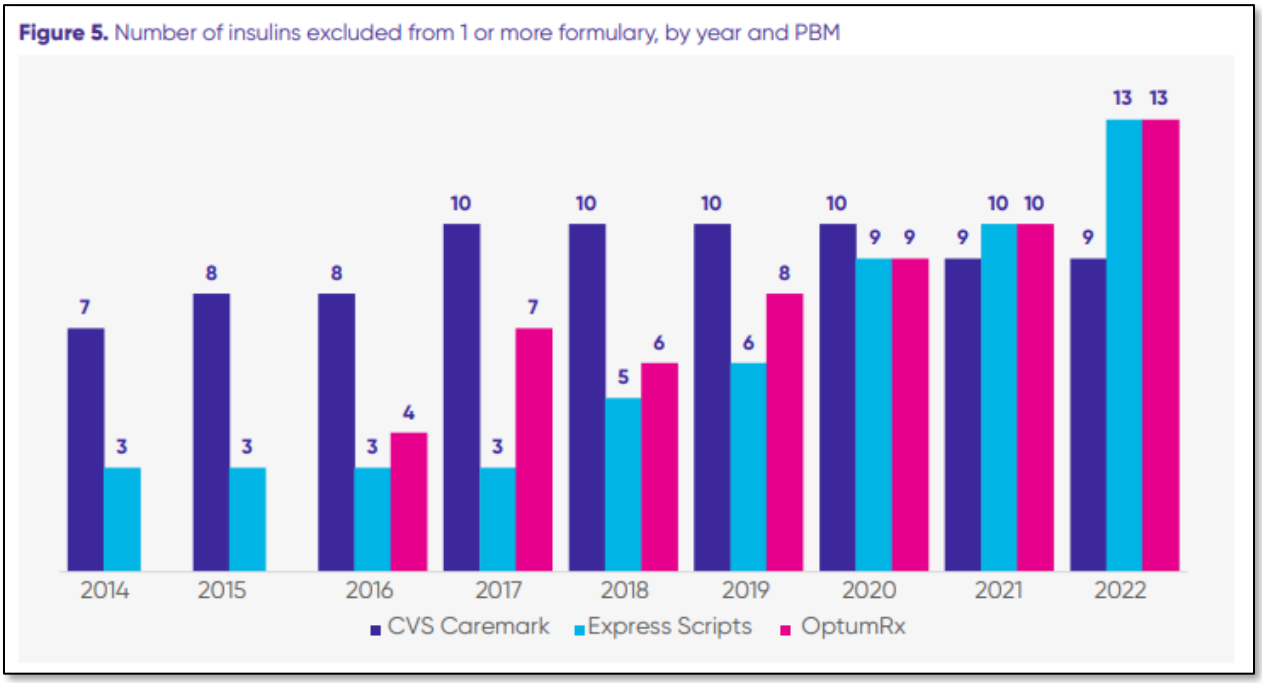
[74] *Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin*, Congress.Gov (Apr. 10, 2019), https://www.congress.gov/event/116th-congress/house-event/109299

> *bona fide* service fees, and specialty pharmacy discounts/fees are all forms of money received by PBMs and rebate aggregators which may not be shared with (or even disclosed to) the plan sponsor. These charges serve to increase the overall costs of drugs, while providing no benefit whatsoever to plan sponsors.[75]

215. The PBM Defendants' actions in excluding lower list price drugs from their formularies demonstrate the Artificial Pricing Scheme and the misaligned incentives that control the relationships between the PBM Defendants and Manufacturer Defendants.

216. In one May 2022 study, for instance, researchers found that the PBM Defendants have excluded from their formularies lower list-price insulins in favor of products with high list prices. The below figure from the study demonstrates the number of insulins excluded from formularies by the PBM Defendants.[76]

Figure 16 - Insulins Excluded from PBM Defendant Formularies



[75] Frier Levitt, LLC, *Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers, and Taxpayers*, Community Oncology Alliance 17-18 (Feb. 2022), https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf.

[76] *Skyrocketing growth in PBM formulary exclusions continues to raise concerns about patient access*, Xcenda (May 2022), https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_pbm_exclusion_may_2022.pdf

217. As the report describes: "2 of the 3 PBMs have excluded the 2 insulin authorized generics from their formulary exclusion lists since 2020, instead favoring the high list-priced equivalents. Remarkably, this was true even though the list prices for these authorized generic insulins can be half the list price of the brand."[77]

218. Further, as described in the same report, after biosimilar insulins were launched in 2021, "[a]ll 3 PBMs excluded the lower-list priced version in 2022, instead choosing to include the identical product with a higher list price."[78]

219. While PBM Defendants capitalize on this scheme to favor higher list price drugs on their formularies, beneficiaries and payors suffer by paying costs based on increasingly inflated list prices.

220. All Defendants benefit from the opacity of the pharmaceutical system and the closely guarded nature of the amounts Manufacturer Defendants pay in rebates and other payments for favorable formulary treatment and the portion of those amounts that the PBM Defendants pocket.

221. Indeed, PBMs have fought to oppose transparency requirements regarding the details of their agreements with manufacturers, insurers, and pharmacies.[79]

222. Yet the PBM Defendants have spoken out of both sides of their mouth on transparency, fighting against it on the one hand, and insisting they are transparent with their payors on the other:

[77] *Id.*
[78] *Id.*
[79] Lydia Ramsey, *One of the largest middlemen in the drug industry just released a video showing why it should be able to remain secretive*, Business Insider (Feb. 9, 2017), https://www.yahoo.com/news/one-largest-middlemen-drug-industry-222205694.html

a. In a 2017 interview, for example, the CEO of Express Scripts claimed that the company's patients "know exactly how the dollars flow" and that the company "support[s] absolute transparency with our clients."[80]

b. CVS claims that as "a pharmacy benefit manager . . . [w]e earn the trust of our customers by prioritizing transparency . . . ."[81]

c. In a statement, the President of OptumRx stated that "[e]very day we strive to show our commitment to our clients, and one element of that commitment is to be open and honest about our pricing structure" and that "[w]e want our clients to fully understand our pricing structure."[82]

223. But far from being transparent, PBM Defendants keep payors, like Baltimore, in the dark about precisely what rebates and other payments they are receiving from manufacturers, including the Manufacturer Defendants.

224. Because payors, like Baltimore, are not involved in the negotiation of the contracts and agreements regarding rebates and other payments from Manufacturer Defendants to PBM Defendants, both have been able to manipulate the agreements to ensure PBM Defendants are able to maximize the amounts they retain. Many payors, including Baltimore, have contracts with PBMs that require the PBMs to pass through "rebates" and/or certain other types of payments. In response, Defendants have worked to relabel what would otherwise be characterized as rebates to minimize the amounts passed through to payors and avoid transparency from narrowly defined

[80] *Express Scripts CEO Tim Wentworth defends role of PBMs in drug prices*, CBS News (Feb. 7, 2017), https://www.cbsnews.com/news/express-scripts-tim-wentworth-pbm-rising-drug-prices-mylan-epipen-heather-bresh/.

[81] *What you need to know about PBMS*, CVS Caremark, https://business.caremark.com/insights/2023/what-you-need-know-about-pbms.html (last visited Feb. 6, 2024).

[82] *Prescription Solutions by OptumRx Receives 4th Consecutive TIPPS Certification for Pharmacy Benefits Transparency Standards*, BusinessWire (Sept. 13, 2011), https://www.businesswire.com/news/home/20110913006224/en/Prescription-Solutions-by-OptumRx-Receives-4th-Consecutive-TIPPSSM-Certification-for-Pharmacy-Benefits-Transparency-Standards

audit rights regarding "rebates" that are present in some payor contracts. As such, rather than simply rebates, Manufacturer Defendants pay to PBM Defendants various payments dubbed "administrative fees," "volume discounts," "service fees," "inflation fees," and other vaguely named categories of reimbursement to disguise the total sums exchanged.

225. These disguised rebates represent a large amount of money retained by PBMs. For example, according to a complaint filed by Express Scripts, administrative fees can dwarf rebates. In just one alleged invoice Express Scripts was seeking payment for in that lawsuit, "administrative fees" were more than three and a half times the amount billed for formulary rebates and price protection rebates ***combined***.[83]

226. Administrative fees, like other payments and fees collected by the PBM Defendants are also normally calculated based on some percentage of the list price of the medications. This again incentivizes the PBM Defendants to provide preferential formulary treatment to drugs with higher list prices so that those drugs are prescribed more than lower-cost drugs, given that the various other payments received by the PBM Defendants that are calculated based on the list price are higher for the more expensive drugs—even where the costs associated with certain services, *i.e.*, "administration" would be the same.

227. Further, and as mentioned above, payments other than those labeled as "rebates" fall beyond a payor's limited contractual audit rights, which are generally limited to "rebates." This means that even the most sophisticated and vigilant payor can neither discover nor challenge these additional agreements.

228. As summarized by one previous DOJ and FTC official:

> PBMs establish tremendous roadblocks to prevent payors from knowing the amount of rebates they secure. Even sophisticated buyers are unable to secure

[83] Complaint, 15, *Express Scripts, Inc. v. Kaleo, Inc.*, No. 4:17-cv-01520 (E.D. Mo. May 16, 2017).

> specific drug by drug rebate information. PBMs prevent payors from being able to audit rebate information. As the Council of Economic Advisors observed, the PBM market lacks transparency as "[t]he size of manufacturer rebates and the percentage of the rebate passed on to health plans and patients are secret." Without adequate transparency, plan sponsors cannot determine if the PBMs are fully passing on any savings, or whether their formulary choices really benefit the plan and subscribers.[84]

2. Rebate Aggregators

229. The PBM Defendants' use of "rebate aggregators" also furthers the Artificial Pricing Scheme and allows for the PBM Defendants to further conceal the nature and extent of fees received from the Manufacturer Defendants from payors, like Baltimore.

230. Rebate aggregators are a more recent development in the pharmaceutical supply chain. These entities, nominally intended to leverage increased negotiating power, are supposedly used by PBMs to outsource negotiating and contracting with drug manufacturers on their behalf. The truth, however, is more insidious. Each of the PBM Defendants has its own affiliated or controlled rebate aggregator. Express Scripts, for example, formed Ascent Health Services GPO in 2019. In 2020, CVS formed Zinc GPO. And in 2021, OptumRx formed Emisar Pharma Services.

231. The PBM Defendants use their affiliate rebate aggregator as a subcontractor to negotiate and collect their rebates. In "exchange" for this service, the aggregator retains some percentage of the rebate received from the manufacturer and passes on some of that rebate to the PBM who then passes through this "rebate" to the client. Thus, the rebate passed through to the client is less than the actual rebate negotiated with the manufacturer, and the difference is retained by the affiliated rebate aggregator.

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[84]Testimony of David A. Balto, Hearing Before the United States Senate Committee on Commerce, Science, and Transportation: Subcommittee Consumer Protection, Product Safety, and Data Security, entitled "Ensuring Fairness and Transparency in the Market for Prescription Drugs," May 5, 2022, https://www.commerce.senate.gov/services/files/5807DDD6-EA20-42A4-97B1-73541F832839.

232. These rebate aggregators are increasingly used by PBMs. Indeed, in a May 10, 2023, Hearing before the Senate Health, Education, Labor, and Pensions Committee, the CEO of Eli Lilly noted that most of the rebate checks paid by the company in 2022 went to rebate aggregators rather than directly to PBMs.[85]

233. The dealings between PBMs and their rebate aggregators happen behind a veil of secrecy. The amount of rebates retained by aggregators, the payments aggregators may make to PBMs not classified as "rebates," and the contracts between these entities are not made available to payors, like Baltimore. Accordingly, PBMs can, and on information and belief, do, use these rebate aggregators to conceal payments and falsely claim that all or substantial portions of rebates are being passed through to payors.

3. Spread Pricing

234. Spread pricing is another way through which the PBM Defendants profit from the Artificial Pricing Scheme.

235. PBMs, including the PBM Defendants, determine which pharmacies to include in their network and the amounts those network pharmacies are reimbursed for drugs they dispense (typically an amount determined as a percentage of the list price).

236. With spread pricing, PBMs charge payors, like Baltimore, more for a drug (again, typically based on a percentage of the list price) than the PBMs pay to the pharmacies. The PBMs then pocket the difference.

237. Because the amounts charged to payors and pharmacies are typically calculated based on a percentage of the list price, the greater the list price of a drug is, the greater the "spread"

[85]Arthur Allen, *A more aggressive FTC is starting to target drug mergers and industry middlemen*, Health News Florida (May 24, 2023), https://health.wusf.usf.edu/health-news-florida/2023-05-24/a-more-aggressive-ftc-is-starting-to-target-drug-mergers-and-industry-middlemen.

that is pocketed by the PBMs. This further incentivizes PBMs to encourage manufacturer list price increases by treating drugs with higher list prices more favorably on their formularies.

238. As is the case with manufacturer payments not formally classified as rebates or manufacturer rebates that are laundered through rebate aggregators, there is not transparency for payors regarding spread pricing. And because the amount obtained through spread pricing is not classified as a "rebate," it is not passed through to payors.

4. Mail-Order Profits

239. Defendant PBMs also profit from the Artificial Pricing Scheme by selling the subject diabetes medications through their own pharmacies.

240. At its most basic, the false and inflated list prices set as part of the Artificial Pricing Scheme led to increased amounts paid by customers, such as Baltimore, for those medications, leading to the realization of higher profits for the PBM Defendants' pharmacies.

241. Manufacturer Defendants are also charged fees by the PBM Defendants related to mail-order pharmacy services. These fees, like other fees previously discussed, are tied to the list price of drugs. Accordingly, PBM Defendants again make greater profits as list prices increase.

242. All told, the entirety of the Artificial Pricing Scheme and the ways Defendants have profited immensely therefrom is deceptive and unconscionable.

G. Baltimore's Purchase of Insulin and Diabetes Medications from Defendants

243. As previously alleged, Baltimore offers more than 60,000 employees, retirees, and associated dependents pharmaceutical benefits through its self-funded insurance plan each year. Because Baltimore uses a self-funded plan, Baltimore, rather than a third-party insurer, pays for its portion of its beneficiaries' prescription drugs.

244. Over the relevant period, Baltimore has used both Express Scripts (2006-2017) and CVS (2018-Current), as well as pharmacies within their network and/or corporate family, for their services and the subject diabetes medications. Baltimore utilized Express Scripts, and later CVS, to help control the costs of prescription medications associated with the pharmaceutical benefits it provides to its beneficiaries and efficiently and effectively administer Baltimore's pharmaceutical benefits. As part of the services provided to Baltimore, Express Scripts, and later CVS, managed the formulary for Baltimore's pharmaceutical benefits, constructed and managed Baltimore's pharmacy network (including by dispensing the subject diabetes drugs through Express Scripts and CVS pharmacies), and processed pharmacy claims.

245. As part of Baltimore's pharmaceutical benefits, Baltimore pays for a large portion of the pharmaceutical purchases of its beneficiaries. After beneficiaries pay their portion of the costs of the subject diabetes medications, Baltimore pays the remaining portion. Baltimore pays these amounts regularly.

246. Baltimore has spent an enormous amount on the subject diabetes medications on behalf of its beneficiaries. The gross cost to Baltimore for the subject diabetes medications from January to October 2023, for instance, was more than $11,000,000.

247. By purchasing the subject diabetes medications through Express Scripts and CVS, Baltimore has suffered loss because of the false and inflated prices caused by the Artificial Pricing Scheme. Baltimore paid Express Scripts and CVS the false and inflated costs caused by the Artificial Pricing Scheme because Baltimore's payments are derived from the inflated list prices of the subject diabetes drugs.

248. Both Express Scripts and CVS participated in the Artificial Pricing Scheme, which increased the prices paid by Baltimore for the subject diabetes medications.

249. Unlike Baltimore, Defendants have suffered no losses from the Artificial Pricing Scheme. Rather, Defendants have benefited from the scheme at the expense of beneficiaries and payors, including Baltimore. Despite their duties as the PBMs Baltimore contracted with to limit its pharmaceutical drug costs and ease its administrative burden, CVS and Express Scripts participated and benefited from the Artificial Pricing Scheme in direct contravention of their commitments to Baltimore.

H. Defendants' Deception

250. Defendants have not disclosed the Artificial Pricing Scheme, the nature and origin of the false and inflated prices of the subject diabetes medications produced by the Scheme, and Defendants' roles in creating and perpetuating the Artificial Pricing Scheme. Rather, Defendants have actively worked to deceive payors (including Baltimore) and others in furtherance of the Artificial Pricing Scheme through misrepresentations and omissions, including those previously alleged in this Complaint.

1. Manufacturer Defendants' Misrepresentations and Omissions

251. Throughout the relevant period, the Manufacturer Defendants knew that the purchase price paid by payors and the Manufacturer Defendants' own list prices were false, inflated, and not based on any competitive, fair market price for the subject diabetes medications.

252. The Manufacturer Defendants further knew payors, including Baltimore, relied on the false and inflated list prices produced by the Artificial Pricing Scheme (and the other prices and fees based on the false and inflated list prices) in paying for the subject diabetes medications.

253. Yet, as the Manufacturer Defendants also knew, these prices were completely untethered from the actual costs incurred, were artificially inflated solely to produce additional profits for Defendants as part of the Artificial Pricing Scheme, and were not the result of any legitimate, transparent, or competitive market forces.

254. Further, all Defendants knew that Baltimore and other payors desired to pay fair prices for the subject diabetes medications and expected the PBM Defendants to negotiate the lowest reasonable prices for these medications, reflecting the drugs' market value and the economies of scale and bargaining power of the PBMs.

255. Though they knew of the false and inflated nature of the list prices produced through the Artificial Pricing Scheme, the Manufacturer Defendants nevertheless published those prices throughout the country, including in Maryland, in medical pricing compendia, promotional and marketing materials, and in direct communications to pharmacies and PBMs.

256. PBMs and pharmacies used the false and inflated list prices published by the Manufacturer Defendants and PBMs to set the prices they charge for the subject diabetes medications to payors, like Baltimore.

257. By publishing their prices throughout the United States and in Maryland, the Manufacturer Defendants held these prices out as a fair and reasonable price for the subject diabetes medications.

258. Each of these representations was false. As the Manufacturer Defendants knew, the false and inflated list prices were untethered from the fair market value of the drugs, unrelated to the drugs' cost, and significantly higher than the net price the Manufacturer Defendants received for those same drugs. Indeed, during the relevant period, the subject diabetes medications were being sold profitably in other countries for a fraction of their list prices in the United States. And the Manufacturer Defendants could have sold these same drugs profitably in the United States at similarly reduced levels, given the low costs of production.

259. As previously stated, the Manufacturer Defendants have publicly claimed that increases in the prices of the subject diabetes medications are based on research and development

costs. Briefing materials prepared by Eli Lilly for a presentation by its CEO at a 2017 summit on pricing, for example, emphasized research and development costs for insulin.[86] Similarly, in testimony before the House Energy and Commerce Subcommittee on April 10, 2019, Sanofi's Executive Vice President for External Affairs represented that a component of raising list prices was "the need to continue to invest in R&D."[87]

260. Such representations are false. Between 2005 and 2018, Eli Lilly's research and development costs for Humalog were the equivalent of only 3.6% of the drug's net sales in the U.S. alone over the same period. Similarly, Sanofi's research and development expenditures related to Lantus between 1990 and 2018 were the equivalent of just 2.4% of the drug's net sales in the U.S. alone over that period. And Novo Nordisk spent significantly more on buybacks and dividends than it did on research and development costs between 2016 and 2020.[88]

261. Indeed, as the Oversight Committee Report that detailed an investigation into the drug pricing practices of manufacturers, including the Manufacturer Defendants, explained: "When facing criticism over its pricing practices, the pharmaceutical industry claims that high drug prices are necessary to fund innovative research and development (R&D) for new therapies and to recoup other supply chain costs. The Committee's investigation found that these justifications for high prices are unsupported . . . ."[89]

262. At bottom, payors, including Baltimore, relied on the Manufacturer Defendants' misrepresentations and omissions made in furtherance of the Artificial Pricing Scheme in purchasing the subject diabetes medications.

[86]Oversight Report, *supra* note 12 at 169.
[87]*Insulin Costs*, CSPAN (Apr. 10, 2019), https://www.c-span.org/video/?459672-1/insulin-costs.
[88] Oversight Report, *supra* note 12 at 167, 169-72.
[89]*Id.* at 164.

2. PBM Defendants' Misrepresentations and Omissions

263. The PBM Defendants promoted the Manufacturer Defendants' false and inflated list prices for the subject diabetes medications by favoring higher-list price drugs in formulary construction and using the false and inflated list prices as the basis for determining costs for payors, like Baltimore.

264. The PBM Defendants further promoted the false and inflated list prices by negotiating rebates and other payments that they then failed to pass through in full to payors, like Baltimore, based on those list prices rather than negotiating to lower list prices.

265. The PBM Defendants utilize and encourage the Manufacturer Defendants' false and inflated list prices for the subject diabetes medications because it allows the PBM Defendants to obtain greater profits through increased rebates and other payments extracted from the Manufacturer Defendants and prices charged to payors, like Baltimore, for the drugs themselves as well as other fees calculated based on the false and inflated list prices.

266. The proliferation of the false and inflated list prices also ensures all Defendants are able to perpetuate the Artificial Pricing Scheme through a lack of transparency into the net amounts exchanged between the PBM Defendants and the Manufacturer Defendants for the subject diabetes medications.

267. During the relevant period, the PBM Defendants and their corporate families have consistently and falsely represented in their SEC filings that they negotiate with the Manufacturer Defendants and structure their formularies in ways that lower the prices for payors and beneficiaries and in order to promote health:

a. Express Scripts represents that it reduces the total cost of care for its clients. It claims that it delivers more affordable solutions and that its PBM services offers a more affordable prescription drug benefit for clients. It

claims that it designs formularies with an eye towards cost-effectiveness and affordability after independent physicians and pharmacists have evaluated drugs for safety and efficacy.[90]

b. CVS represents that its PBM services help improve health outcomes while minimizing the costs to the client. It claims that it helps design benefits plans that promote the use of lower-cost clinically appropriate drugs and helps its PBM clients control costs by recommending plan designs that encourage the use of generic equivalents of brand-name drugs. CVS further represents that its formularies' designs help to drive the lowest net costs for clients and that an independent panel of doctors, pharmacists, and other medical experts select drugs for formularies based on safety and efficacy standards.[91]

c. OptumRx claims that its programs help clients manage overall pharmacy costs in a manner designed to deliver better health outcomes and a lower total cost of care. It has represented that it is dedicated to helping customers achieve a low-cost, high-quality pharmacy benefit.[92]

268. The PBM Defendants have made the same or similar misrepresentations in other contexts, including in statements specifically regarding diabetes medications:

a. In an article published on November 28, 2012, regarding CVS's PBM business blocking coverage of drugs, including some for diabetes, CVS

[90] *See* Express Scripts Holding Company Annual Report (Form 10-K) (FYE 12/31/2012); Cigna Annual Report (Form 10-K) (FYE 12/31/2022).
[91] *See* CVS Caremark Corporation Annual Report (Form 10-K) (FYE 12/31/2010); CVS Health Corporation Annual Report (Form 10-K) (FYE 12/31/2022).
[92] *See* UnitedHealth Group Inc. Annual Report (Form 10-K) (FYE 12/31/2010); UnitedHealth Group Inc. Annual Report (Form 10-K) (FYE 12/31/2022).

stated that "managing the formulary is one way the company helps manage costs for clients while maintaining comprehensive coverage for members."[93]

b. In an April 9, 2019, Senate Hearing, an executive from CVS stated, "Our goal as a PBM is simple: to reduce costs and improve health outcomes. We do this by negotiating discounts with manufacturers, designing formularies that encourage the use of generics and biosimilars, and creating new tools to help bring escalating drug prices under control."[94]

c. In an April 10, 2019, Congressional Hearing, an executive from CVS claimed that CVS "has taken a number of steps to address the impact of insulin price increases. We negotiate the best possible discounts off the manufacturers' price on behalf of the employers, unions, government programs, and beneficiaries that we serve."[95]

d. In the same hearing, an executive from Express Scripts represented that "[a]t Express Scripts we negotiate lower drug prices with drug companies on behalf of our clients, generating savings that are returned to patients in the form of lower premiums and reduced out-of-pocket costs."[96]

e. Also in that hearing, an executive from OptumRx testified that "we negotiate with brand manufacturers to obtain significant discounts off list prices on behalf of our customers."[97]

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[93] Jon Kamp & Peter Loftus, *CVS' PBM Business Names Drugs It Plans to Block Next Year*, Wall Street Journal (Nov. 8, 2012), https://www.wsj.com/articles/SB10001424127887324439804578107040729812454.
[94] *Drug Pricing in America: A Prescription for Change, Part III*, United States Senate Comm. On Finance (Apr. 9, 2019), https://www.finance.senate.gov/hearings/drug-pricing-in-america-a-prescription-for-change-part-iii.
[95] *Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin*, *supra* note 74.
[96] *Id.*
[97] *Id.*

f. In the April 9, 2019, Senate Hearing, the CEO of OptumRx stated that OptumRx employees work "to ensure that the people we serve have affordable access to the drugs they need" and that "we negotiate meaningful discounts for manufacturers and prefer the drug with the lowest overall cost on our formularies."[98]

269. As previously noted, the PBM Defendants have further specifically misrepresented that they are not responsible for increasing costs of medications, including the subject diabetes medications:

a. On a February 9, 2017, earnings call the head of CVS claimed, "Any suggestion that PBMs are causing prices to rise is simply erroneous."[99]

b. On a February 15, 2017, earnings call the CEO of Express Scripts said "Drugmakers set prices, and we exist to bring those prices down."[100]

c. In a February 2017, CBS interview the CEO of Express Scripts said the contention that PBMs are playing a part in driving up drug prices "doesn't make sense" and claimed PBMs "negotiate with drug companies . . . to get the prices down."[101]

d. In the April 10, 2019, Congressional Hearing an executive from CVS testified that he did not know why list prices for insulin were high, but that it was not because of rebates.[102]

[98] *Drug Pricing in America: A Prescription for Change, Part III*, *supra* note 94.
[99] Webster, *supra* note 72.
[100] *Id.*
[101] *Express Scripts CEO Tim Wentworth defends role of PBMs in drug prices*, *supra* note 80.
[102] *Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin*, *supra* note 74.

e. In the same hearing, an executive from Express Scripts agreed, testifying "I have no idea why list prices are high and it's not a result of rebate[s]."[103]

f. An executive from OptumRx further testified in the same hearing, "we can't see a correlation just when rebates raise list prices."[104]

270. All of these representations are and have been false, and the PBM Defendants knew as such when making them. Further, all of the PBM Defendants' public statements regarding the pricing of the subject diabetes medications have been consistent with the misrepresentations detailed in this Complaint. The PBM Defendants have never contradicted their misrepresentations or revealed the existence, nature, or scope of the Artificial Pricing Scheme.

271. The PBM defendants know that payors rely on—indeed enter into business relationships expressly for—the PBMs to negotiate the lowest possible prices for drugs, including the subject diabetes medications. The PBMs know that payors rely on them to construct their formularies in furtherance of that mission and to improve access to medications for beneficiaries.

272. Baltimore did, in fact, rely on Express Scripts and CVS for this purpose.

273. As alleged above, the PBM Defendants have also consistently represented that they provide transparency regarding rebates and other payments from the Manufacturer Defendants to payors, like Baltimore:

a. In a February 2017 interview, the CEO of Express Scripts claimed that the company's patients "know exactly how the dollars flow" and that the company "support[s] absolute transparency with our clients."[105]

[103] *Id.*
[104] *Id.*
[105] *Express Scripts CEO Tim Wentworth defends role of PBMs in drug prices*, *supra* note 80.

b. On its website, CVS claims that as "a pharmacy benefit manager . . . [w]e earn the trust of our customers by prioritizing transparency . . . ."[106]

c. In a September 2011 statement, the President of OptumRx stated that "[e]very day we strive to show our commitment to our clients, and one element of that commitment is to be open and honest about our pricing structure" and that "[w]e want our clients to fully understand our pricing structure."[107]

d. In the April 9th, 2019, Senate Hearing, a CVS executive claimed, "as it pertains to transparency overall, we at CVS Caremark are very supportive. We provide full visibility to our clients of all our contracts and the discounts that we negotiate on their behalf."[108]

e. In the same hearing, an executive at OptumRx noted, "Our discounts are transparent to our clients."[109]

f. And in the April 10th, 2019, Congressional Hearing, an executive of Express Scripts testified that "The rebate system is 100 percent transparent to the plan sponsors and the customers that we service. To the people that hire us, employers of America, the government, health plans, what we negotiate for them is transparent to them."[110]

274. In reality, PBM Defendants have not been transparent regarding their ties to the Manufacturer Defendants and participation in the Artificial Pricing Scheme. Rather, they have

[106] *What you need to know about PBMS*, CVS Caremark, https://business.caremark.com/insights/2023/what-you-need-know-about-pbms.html (last visited Feb. 6, 2024).
[107] *Prescription Solutions by OptumRx Receives 4th Consecutive TIPPS Certification for Pharmacy Benefits Transparency Standards*, *supra* note 82.
[108] *Drug Pricing in America: A Prescription for Change, Part III*, *supra* note 94.
[109] *Id.*
[110] *Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin*, *supra* note 74.

offered only vague and misleading disclosures of those ties when any were offered at all. Similarly, the PBM Defendants have narrowly classified "rebates" and other types of payments from the Manufacturer Defendants that the PBM Defendants have a contractual duty to remit to payors. The PBM Defendants received amounts well in excess of those they classified as "rebates" and categorized them differently or laundered them through their affiliated Rebate Aggregators in order to avoid remitting them to payors.

275. During the relevant period, the PBM Defendants made the misrepresentations discussed above and other similar misrepresentations consistently and directly to payors throughout the country, in Maryland, and to Baltimore specifically. These misrepresentations have been made through the media, public filings, bid proposals, communications to payors and beneficiaries, invoices, and formulary change notifications.

276. The representations made by the PBM Defendants are false. Defendants have coordinated to publish and utilize the false and inflated list prices of the subject diabetes medications, exchanged hidden payments and benefits for list price increases and favorable formulary treatment, and worked to cover it all up, leading to the documented excessively inflated prices of the subject diabetes medications.

277. Further evincing the PBM Defendants' role in the Artificial Pricing Scheme, the House Oversight Committee found that federal health programs that were able to negotiate directly with manufacturers saved considerably more money on insulin than Medicare Part D plans (which utilize PBMs). Had the Medicare Part D plans been given the same prices as the federal health programs that directly negotiated with Manufacturers, they would have saved nearly $17 billion over just seven years.[111]

[111] Oversight Report, *supra* note 12 at iv.

278. Defendants know their representations are false, and they knew the representations were false at the time they made them. Indeed, Defendants have coordinated to withhold the truth regarding the Artificial Pricing Scheme from the public, beneficiaries, and payors, including Baltimore.

279. Defendants have concealed the falsity of their representations and the existence of the Artificial Pricing Scheme by protecting and preventing the disclosure of the agreements, pricing negotiations, and flow of money between the Manufacturer Defendants and PBM Defendants. Indeed, to this day, Defendants have never revealed the complete nature and full amount of the rebates and other payments exchanged or the full relevant terms of their agreements.

280. Payors' audit rights of the PBM Defendants are narrow and do not cover the full extent of rebates and other payments exchanged between Defendants.

281. Beneficiaries and payors have no alternative to paying the false and inflated prices generated through the Artificial Pricing Scheme. Beneficiaries need the subject medications to manage their diabetes. Manufacturer Defendants manufacture nearly all of the diabetes medications available in the United States, and PBM Defendants' control over formularies makes the purchase of alternative medications costly, difficult, or impossible.

282. Baltimore did not know, as a result of Defendants' misrepresentations and omissions, that (1) Defendants coordinated to create the PBM formularies in exchange for hidden consideration and that this consideration and high list prices governed the PBM Defendants' formulary determinations; (2) the list prices for the subject diabetes medications were false and inflated; and (3) the list and net prices of the subject diabetes medications were untethered from the fair market value of the drugs and the services provided by the PBMs.

I. The Artificial Pricing Scheme Has Injured Baltimore

283. At all times prior to 2023, Baltimore was unaware of the full nature and extent of the Artificial Pricing Scheme, Defendants' involvement and control over the Scheme, and the false and inflated nature of the prices of the subject diabetes medications that Baltimore was paying because of the Artificial Pricing Scheme.

284. Baltimore relied on the statements and omissions Defendants made in furtherance of the Artificial Pricing Scheme.

285. Baltimore relied on Defendants' misrepresentations in paying for the subject diabetes medications at prices that would have been lower but for Defendants' Artificial Pricing Scheme and that were based on the false and inflated list prices set through the Artificial Pricing Scheme.

286. Payors, including Baltimore, and their beneficiaries, were the direct and intended victims of the Artificial Pricing Scheme.

287. Defendants' relationships with Baltimore were and are inherently unbalanced. Both Express Scripts and CVS have superior bargaining power and superior knowledge regarding their relationships with the Manufacturer Defendants, who ultimately set the false and inflated list prices upon which the costs of the subject diabetes medications borne by Baltimore were established. CVS and Express Scripts knew about the Artificial Pricing Scheme and the false and inflated list prices of the subject diabetes medications and failed to disclose the details of this scheme and the full nature of their financial relationships with the Manufacturer Defendants to Baltimore. Express Scripts and CVS exploited their superior bargaining positions to mislead Baltimore and contravene Baltimore's expectations, to Baltimore's great expense and detriment.

288. In Baltimore's role as a payor for the subject diabetes medications, Defendants' misrepresentations, omissions, and misconduct related to and in furtherance of the Artificial Pricing Scheme proximately caused economic damage to Baltimore.

289. A significant degree of the funds paid by Baltimore for the subject diabetes medications is attributable solely to the Artificial Pricing Scheme and the resulting false and inflated list prices of the subject diabetes medications.

290. Because of Defendants' fraudulent and wrongful acts and omissions concealing the Artificial Pricing Scheme, Baltimore could not have known that the prices it paid for the subject diabetes medications were artificially inflated.

291. Though Baltimore received some amounts of payments made from Manufacturer Defendants to Express Scripts and CVS that were properly labeled and passed through to Baltimore per the terms of its agreements with those PBMs, Baltimore was nevertheless overcharged for the subject diabetes medications, which would have cost less but for the Artificial Pricing Scheme and Defendants' actions in furtherance thereof.

292. The Artificial Pricing Scheme has directly and proximately caused Baltimore to overpay for the subject diabetes medications. And because Defendants continue to produce false and inflated list prices for the subject diabetes medications as part of the Artificial Pricing Scheme, the harm to Baltimore is ongoing.

J. The Manufacturer Defendants' Recent Actions are Insufficient

293. In the past year, the Manufacturer Defendants have announced some efforts, in response to outcry and government investigation, that they represented would lower prices and out-of-pocket costs for patients.

294. In a March 1, 2023, news release, Eli Lilly stated that it would cap patient out-of-pocket insulin costs at $35 per month and cut insulin prices by 70%. Specifically, Eli Lilly claimed

it would change the list price of its non-branded insulin to $25 a vial, cut the price of Humalog and Humulin by 70%, and launch a biosimilar to Lantus at a discount of 78% off the price of the brand drug.[112] These discounts are insufficient. They are solely forward-looking, only cover some of Eli Lilly's diabetes drugs, still represent inflated prices for the branded drugs considering the costs of production and are strong evidence that Eli Lilly's prices before these discounts were imposed were even more supracompetitive.

295. Following Eli Lilly, in a March 14, 2023, announcement, Novo Nordisk also stated that it would reduce prices up to 75% on some of its insulins effective January 1, 2024. The medications Novo Nordisk announced it would discount included Levemir, Novolin, NovoLog, and NovoLog Mix 70/30. It also stated it would lower the prices of its unbranded insulins to match the changes for the respective branded drugs.[113] Like Eli Lilly's, these discounts are insufficient. They are solely forward-looking, only cover some of Novo Nordisk's diabetes drugs, still represent inflated prices for the drugs considering the costs of production and are strong evidence that Novo Nordisk's prices before these discounts were imposed were even more supracompetitive.

296. Shortly after Novo Nordisk's announcement, Sanofi followed suit and, on March 16, 2023, announced that it would cut the list price of Lantus by 78% and cap out-of-pocket costs for patients with commercial insurance beginning January 1, 2024.[114] These discounts too are insufficient. Again, these discounts are forward-looking, only cover some of Sanofi's diabetes drugs, still represent inflated prices for the drugs considering the costs of production and are strong

[112]*Lilly Cuts Insulin Prices by 70% and Caps Patient Insulin Out-of-Pocket Costs at $35 Per Month*, Eli Lilly (Mar. 1, 2023), https://investor.lilly.com/news-releases/news-release-details/lilly-cuts-insulin-prices-70-and-caps-patient-insulin-out-pocket.
[113]*Novo Nordisk to lower U.S. prices of several pre-filled insulin pens and vials up to 75% for people living with diabetes in January 2024*, Novo Nordisk (Mar. 14, 2023), https://www.novonordisk.com/news-and-media/latest-news/lowering-us-list-prices-of-several-products-.html.
[114]*Sanofi cuts U.S. list price of Lantus, its most-prescribed insulin, by 78% and caps out-of-pocket Lantus costs at $35 for all patients with commercial insurance*, Sanofi (Mar. 16, 2023), https://www.sanofi.com/en/media-room/press-releases/2023/2023-03-16-20-06-43-2629188.

evidence that Sanofi's prices before these discounts were imposed were even more supracompetitive.

V. STATUTE OF LIMITATIONS TOLLING

297. Baltimore diligently pursued and investigated the claims asserted in this Complaint. Through no fault of its own, Baltimore did not receive any inquiry notice or learn of the factual basis for the claims asserted in this Complaint and the injuries suffered until recently. Accordingly, the following doctrines tolling any applicable statute of limitations apply.

A. Discovery Rule

298. Baltimore was unaware of the extent of the Artificial Pricing Scheme, the extent to which it was economically injured, and that it was caused any economic injury through wrongful conduct until shortly before preparing and filing this Complaint. Baltimore did not possess sufficient information concerning the injury complained of here or its cause to put Baltimore or any reasonable person on notice that actionable conduct might have occurred.

299. Defendants actively worked to conceal the Artificial Pricing Scheme from Baltimore and others. Defendants refused to disclose the actual prices of the subject diabetes medications, the details of the Defendants' negotiations and payments between each other, the pricing structures and agreements that governed the relationships between the Defendants, the full extent to which inflated list prices influenced the PBM Defendants' formulary determinations and other aspects of the Artificial Pricing Scheme. To protect the details of their scheme, Defendants labeled prices trade secrets, entered into confidentiality agreements, limited payor audit rights, and otherwise impeded ways through which the details of the Artificial Pricing Scheme and its features would be revealed.

300. PBM Defendants and Manufacturer Defendants have affirmatively blamed each other for the inflated prices of the subject diabetes medications through the media, Congressional

testimonies, and other forums. Each group of Defendants has denied wrongdoing and asserted—falsely—that their dealings with payors like Baltimore were honest and transparent.

301. Baltimore did not discover facts sufficient to cause a reasonable person to suspect that Defendants were engaged in the Artificial Pricing Scheme or that Baltimore had suffered economic injury as a result of Defendants' wrongdoing until shortly before filing this Complaint. Even had Baltimore been aware of any cause to undertake a diligent inquiry, such an inquiry would not have disclosed the true facts, particularly given Defendants' efforts to conceal the Artificial Pricing Scheme.

302. Defendants continue their attempts to conceal the Artificial Pricing Scheme and their wrongful conduct in furtherance thereof. The lack of transparency regarding the pricing of the subject diabetes medications and the agreements and actions that make up the Artificial Pricing Scheme continue to shield the extent of Defendants' wrongdoing from Baltimore and the public.

303. Accordingly, because Baltimore did not and could not have discovered the Artificial Pricing Scheme or the injuries it suffered, the applicable statute of limitations did not begin to run until, at the earliest, 2023.

B. Fraudulent Concealment

304. Through the acts, omissions, and misrepresentations alleged herein, Defendants fraudulently concealed the fact of Baltimore's injury and its cause: the Artificial Pricing Scheme.

305. Because Defendants took efforts to purposefully conceal the Artificial Pricing Scheme, their setting of the false and inflated list prices, and the fact that the prices of the subject diabetes medications were inflated through the Artificial Pricing Scheme, Defendants cannot rely on a statute of limitations defense.

306. Defendants knowingly and fraudulently concealed the wrongful acts set forth in this Complaint. Defendants had material information pertinent to the discovery of these wrongful

acts and nevertheless concealed that information from Baltimore. Baltimore did not know of, and could not have discovered through the exercise of reasonable diligence, the existence or scope of the Artificial Pricing Scheme or Baltimore's causes of action because of Defendants' conduct in fraudulently concealing the Artificial Pricing Scheme.

307. Baltimore was unable to obtain vital information bearing on its claims without any fault or lack of diligence on its part as Defendants secretly engaged in the Artificial Pricing Scheme. Only Defendants and their agents knew about or could have discovered Defendants' unlawful actions because of Defendants' deliberate efforts to conceal their conduct and the existence of the Artificial Pricing Scheme.

308. As alleged in this Complaint, Defendants affirmatively and fraudulently concealed: (i) that the Defendants coordinated to create the PBM Defendants' formularies to favor diabetes medications with higher list prices in exchange for consideration; (ii) that the list prices set by Defendant Manufacturers for the subject diabetes medications were false and inflated; (iii) that the prices paid by payors, including Baltimore, were untethered to the fair market value of the subject diabetes medications and the services rendered by the PBM Defendants in coordinating the prices of those drugs; and (iv) that the subject diabetes drugs were selected for favorable treatment and inclusion on the PBM Defendants' formularies because of their false and inflated list prices rather than because they were more cost-effective or better diabetes treatments.

309. As alleged in this Complaint, PBM Defendants concealed the Artificial Pricing scheme by hiding payments made to them by Manufacturer Defendants, which were not passed on to payors as promised.

310. Baltimore acted diligently in pursuing this action once it learned facts sufficient to place it on notice that it had been harmed, the extent of that harm, and that the harm may be attributable to the Defendants' misconduct.

311. Given Defendants knowingly concealed the facts essential to Baltimore's claims, Defendants cannot claim any prejudice due to an alleged late filing.

312. Any applicable statutes of limitations, therefore, have been tolled.

C. Equitable Estoppel

313. Defendants had a continuing duty to disclose to Baltimore the true character, quality, and nature of the prices upon which the payments for the subject diabetes medications were based, and the true nature of the PBM services provided. All of these facts were and are material to Baltimore.

314. However, rather than disclose these facts, Defendants made knowing misrepresentations and worked to actively conceal the truth. Defendants did so knowing and expecting that payors, like Baltimore, would act upon their misrepresentations and omissions.

315. And Baltimore did rely on Defendants' misrepresentations and omissions, unaware of the truth and the extent (or existence) of the economic harm it suffered.

316. Through their acts, omissions, and misrepresentations, Defendants knowingly misrepresented and actively concealed material facts with the expectation that Baltimore would act upon them. Baltimore did so in good faith and to its detriment.

317. As such, Defendants are equitably estopped from relying on any statutes of limitations in their defense, and all such statutes of limitations have been equitably tolled.

D. Continuing Violations

318. The acts, omissions, misrepresentations, and concealment alleged above have continued to the present. The systematic misconduct by Defendants is a continuous, unbroken violation of law that continues to cause economic harm to Baltimore.

319. Any applicable statutes of limitations, therefore, are tolled.

VI. CLAIMS FOR RELIEF

COUNT ONE

VIOLATIONS OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT ("RICO") 18 U.S.C. § 1962(c) (Against All Defendants)

320. Plaintiff refers to Paragraphs 1 through 319 above and incorporates the same herein by this reference as set forth in full.

321. As detailed below, Defendants are (1) culpable persons who (2) willfully and knowingly (3) committed and conspired to commit two or more predicate acts, (4) through a pattern of racketeering activity that (5) involves a distinct association in fact enterprise (6) and that had an effect on interstate commerce.

322. Accordingly, Defendants are liable for violations of 18 U.S.C. § 1962(c).

A. Defendants Are Persons for the Purposes of RICO and Distinct from the Alleged Enterprises

323. Each Defendant is a "person" as defined by 18 U.S.C. § 1961(3) as they are "entit[ies] capable of holding a legal or beneficial interest in property."

324. Each Defendant is a distinct and separate entity from the enterprises alleged below.

B. Defendants' Association in Fact Enterprises

325. The RICO enterprises alleged are separate associations-in-fact consisting of one of each of the Manufacturer Defendants and one of each of the PBM Defendants—including those

entities' agents, employees, and directors. Thus, there are nine association-in-fact enterprises, as reflected below, collectively referred to as the "PBM-Manufacturer Enterprises."

	Eli Lilly Enterprises	Novo Nordisk Enterprises	Sanofi Enterprises
CVS Enterprises	Eli Lilly-CVS Enterprise	Novo Nordisk-CVS Enterprise	Sanofi-CVS Enterprise
Express Scripts Enterprises	Eli Lilly-Express Scripts Enterprise	Novo Nordisk-Express Scripts Enterprise	Sanofi-Express Script Enterprise
OptumRx Enterprises	Eli Lilly-OptumRx Enterprise	Novo Nordisk-OptumRx Enterprise	Sanofi-OptumRx Enterprise

326. Each PBM-Manufacturer Enterprise is a separate, ongoing, and continuing business organization consisting of the respective corporations and individuals associated for a common purpose.

a. The Eli Lilly-CVS Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of the subject diabetes medications manufactured by Eli Lilly, including Humulin R, Humulin R 500, Humulin N, Humulin 70/30, Humalog, Basaglar, and Trulicity.

b. The Eli Lilly-Express Scripts Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of the subject diabetes medications manufactured by Eli Lilly, including Humulin R, Humulin R 500, Humulin N, Humulin 70/30, Humalog, Basaglar, and Trulicity.

c. The Eli Lilly-OptumRx Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of the subject diabetes medications manufactured by Eli Lilly, including

Humulin R, Humulin R 500, Humulin N, Humulin 70/30, Humalog, Basaglar, and Trulicity.

d. The Novo Nordisk-CVS Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of the subject diabetes medications manufactured by Novo Nordisk, including Novolin R, Novolin N, Novolin 70/30, Novolog, Fiasp, Levemir, Tresiba, Victoza, and Ozempic.

e. The Novo Nordisk-Express Scripts Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of the subject diabetes medications manufactured by Novo Nordisk, including Novolin R, Novolin N, Novolin 70/30, Novolog, Fiasp, Levemir, Tresiba, Victoza, and Ozempic.

f. The Novo Nordisk-OptumRx Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of the subject diabetes medications manufactured by Novo Nordisk, including Novolin R, Novolin N, Novolin 70/30, Novolog, Fiasp, Levemir, Tresiba, Victoza, and Ozempic.

g. The Sanofi-CVS Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of the subject diabetes medications manufactured by Sanofi, including Apidra, Lantus, Toujeo, and Soliqua.

h. The Sanofi-Express Scripts Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of the

subject diabetes medications manufactured by Sanofi, including Apidra, Lantus, Toujeo, and Soliqua.

i. The Sanofi-OptumRx Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of the subject diabetes medications manufactured by Sanofi, including Apidra, Lantus, Toujeo, and Soliqua.

327. Every PBM-Manufacturer Enterprise had the shared purpose of exchanging false, artificially inflated list prices as well as rebates and other payments in exchange for favorable formulary treatment for the subject diabetes medications and ultimately profiting off of the buyers of these medications such as payors, like Baltimore. The profits derived through each of the PBM-Manufacturer Enterprises are greater than either respective Manufacturer Defendant or PBM Defendant could obtain absent their misrepresentations regarding the pricing of the subject diabetes medications and concealment of the Artificial Pricing Scheme.

328. To accomplish the common purpose of the PBM-Manufacturer Enterprises, each Manufacturer Defendant inflated the prices of the subject diabetes medications and paid a significant undisclosed portion of the inflated prices to the PBM Defendants as rebates or other payments. The Manufacturer Defendants did so willfully and with the knowledge that consumers and payors like Baltimore paid for the subject diabetes medications based on prices derived from the false and inflated list prices.

329. The inflation of list prices and rebates and other payments by Manufacturer Defendants as part of the PBM-Manufacturer Enterprises was in exchange for favorable treatment on the PBM Defendants' formularies.

330. Every PBM-Manufacturer Enterprise actively concealed and failed to disclose material information from consumers and payors, like Baltimore. This information includes that favorable formulary treatment was the result of increased list prices and large rebates and payments rather than fair market competition through price reductions and that PBM Defendants' earnings were increased in direct relation to list price increases of the subject diabetes medications and increased payments from Manufacturer Defendants.

331. Every PBM-Manufacturer Enterprise shares the additional common purpose of perpetuating the use of the false and inflated list prices for the subject diabetes medications. Absent the use of the false and inflated list prices as the basis for the price paid by consumers and payors, like Baltimore, the Manufacturer Defendants would be unable to offer the large net pricing spreads to PBM Defendants as a quid pro quo for preferential treatment on the PBM Defendants' formularies.

332. The PBM Defendants share this common purpose. The revenue and profits of the PBM Defendants are directly correlated to the false and inflated prices set by the Manufacturer Defendants as part of the Artificial Pricing Scheme. Because PBM Defendants garner revenue tied to the list prices of the drugs sold to payors, absent the Artificial Pricing Scheme, the profits of PBM Defendants would decrease. Accordingly, the PBM Defendants have, with the knowing and willing participation and assistance of the Manufacturer Defendants, engaged in hidden profit-making methods including: (i) garnering undisclosed rebates and other payments from Manufacturer Defendants retained, in large part, by PBM Defendants; (ii) failing to disclose and relabeling rebates and other payments from Manufacturer Defendants to avoid passing through contractually promised percentages of those payments to payors, such as Baltimore; (iii) generating profits on the subject diabetes medications from pharmacies as a result of the false

and inflated prices; (iv) generating profits on the subject diabetes medications sold through the PBM Defendants' and their affiliates' own retail and mail-order pharmacies; and (v) keeping hidden discounts provided by Manufacturer Defendants related to the PBM Defendants' retail and mail-order pharmacy operations.

333. Alone, none of the Defendants could have accomplished the purposes of the PBM-Manufacturer Enterprises without the participation of their counterpart in the respective enterprise.

334. Every PBM-Manufacturer Enterprise was operated and conducted for unlawful or criminal purposes, namely, carrying out the Artificial Pricing Scheme.

335. Each of the PBM-Manufacturer Enterprises has a systematic linkage as the members are bound by contractual relationships, financial ties, and continuing coordination of activities.

336. There is a common communication network by which the members of each PBM-Manufacturer Enterprise share information on a regular basis. These communications include, but are not limited to, those at the heart of the Artificial Pricing Scheme: communications relating to the use of the false and inflated list prices for the subject diabetes medications and the exchange of rebates and other payments from Manufacturer Defendants to PBM Defendants for favorable treatment on their formularies.

337. Separate from the racketeering activity at issue, the PBM-Manufacturer Enterprises function as continuing but separate units. For instance, they engage in the manufacture, sale, and distribution of other medications and products.

338. Every Defendant is and has been aware of the conduct of the respective member of their PBM-Manufacturer Enterprise and has participated in, coordinated, and profited knowingly and willingly from that conduct.

C. Misrepresentations and Omissions of Material Facts in Furtherance of the Artificial Pricing Scheme

339. All PBM-Manufacturer Enterprises knowingly made material misrepresentations and omissions of material fact to the public, consumers, and payors, like Baltimore, by publishing the false and inflated prices for the subject diabetes medications on published drug pricing indices as well as through representations including or regarding:

a. The net prices of the subject diabetes medications;

b. That the false and inflated list prices of the subject diabetes medications were related to fair market prices and the actual prices realized by Defendants;

c. That the PBM Defendants and Manufacturer Defendants negotiated discounts to the list prices of the subject diabetes drugs—and other payments—in good faith and for a proper purpose.

d. That the false and inflated list prices of the subject diabetes medications were a fair and reasonable basis on which to set the prices paid by both payors, including Baltimore, and other consumers;

e. The extent of the difference between the list and net prices of the subject diabetes medications;

f. That PBM Defendants structured their formularies to lower the price of the subject diabetes medications and promote safe and effective diabetes care;

g. That Manufacturer Defendants priced the subject diabetes drugs according to their value and the need to fund research and development;

h. That payments made by Manufacturer Defendants to PBM Defendants were for the benefit of payors, like Baltimore, and saved payors, like Baltimore, money;

i. That the rebates and discounts negotiated by the PBM Defendants were properly accounted for and remitted to payors, like Baltimore;

340. Further, every false and inflated list price published by the Manufacturer Defendants, whether to drug price compendia, the public, or any other audience, is its own distinct material misrepresentation. Such publications held out the false and inflated list prices as the fair market price for the subject diabetes medications, concealing or omitting to disclose material information about the large and fraudulent spread between the list prices published and the net prices actually received by the Manufacturer Defendants and the reasons for those discrepancies. Additional misrepresentations and omissions of material facts made by Defendants are alleged throughout this complaint.

341. At all relevant times, the PBM-Manufacturer Enterprises knew the described representations were false and omitted material information and made such representations to induce consumers and payors, like Baltimore, into paying the false and inflated prices for the subject diabetes medications.

342. And indeed, Baltimore did rely on the material misrepresentations and omissions made by the PBM-Manufacturer Enterprises in expending millions of dollars on the subject diabetes medications based on the false and inflated prices resulting from the Artificial Pricing Scheme.

343. Given that the PBM-Manufacturer Enterprises raised the prices of the subject diabetes medications in lockstep, relying on the list prices published by the other PBM-Manufacturer Enterprises to set their own list prices, rebates, and other payments Baltimore was further injured by the false and inflated prices that resulted from each PBM-Manufacturer Enterprise.

344. Baltimore, other payors, and consumers would not have been willing to pay the false and inflated list prices absent the misrepresentations made by the PBM-Manufacturer Enterprises and their concealment of the Artificial Pricing Scheme. As such, absent these misrepresentations and material omissions, the PBM-Manufacturer Enterprises could not have achieved their respective common purposes.

D. Defendants' Use of U.S. mails and Interstate Wire Facilities

345. The PBM-Manufacturer Enterprises engaged in and affected interstate commerce by conducting activities across state borders, including: purchasing, selling, and administrating the sale of the subject diabetes medications; setting and publishing the prices of the subject diabetes medications and transmitting that pricing information; publishing, transmitting, and receiving marketing and sales materials and literature; transmitting and receiving invoices, payments, and other such documents related to the sale, use, or administration of the subject diabetes medications; transmitting, and receiving contracts, agreements, and negotiations for those contracts and agreements, related to the prices of and payment for the subject diabetes medications; and transmitting the subject diabetes medications through both mail-order and retail pharmacies.

346. The PBM-Manufacturer Enterprises spanned the nation, and each Enterprise assisted in administrating the subject diabetes medications throughout the country and in Maryland.

347. Defendants' unlawful and wrongful conduct was carried out and perpetuated by employees working across state boundaries that relied upon the transfer of information, documents, funds, and products through U.S. mail and interstate wire facilities.

348. The nature of the Artificial Pricing Scheme required Defendants' corporate headquarters and operational centers to communicate directly and frequently by U.S. mail and interstate wire facilities with each other, their employees (including employees in Maryland), and interested individuals and entities, including pharmacies, physicians, payors, consumers, and potential consumers, throughout the country.

349. The use of U.S. mail and interstate wire facilities to effectuate and perpetuate the Artificial Pricing Scheme necessarily involved thousands of communications transmitted through those means by the PBM-Manufacturer Enterprises. Such communications include, but are not limited to:

a. Transmissions regarding the publication of list prices to third parties, including drug price compendia and payors, like Baltimore;

b. Transmission of marketing materials regarding the published prices of the subject diabetes medications;

c. Transmission of the proceeds of the Artificial Pricing Scheme;

d. Transmission of receipts, invoices, and statements related to the sale of and payment for the subject diabetes medications and the rebate and other payments received;

e. Written and oral communications regarding the false and inflated list prices of the subject diabetes medications;

f. Written and oral communications regarding the treatment of the subject diabetes medications on PBM Defendants' formularies;

g. Written and oral communications regarding the rebate and other payments made to PBM Defendants in exchange for the favorable treatment of the subject diabetes medications on their respective formularies and the concealment thereof;

h. Written and oral communications regarding the payment of the rebate and other payments;

i. Written and oral communications relating to rebates and other payments provided to PBM Defendants for their advocacy for the subject diabetes medications;

j. Written and oral communications to payors, like Baltimore, regarding the pricing of the subject diabetes medications;

k. Written and oral communications to payors, like Baltimore, regarding the amount, existence, and purpose of rebates and other payments paid by Manufacturer Defendants to PBM Defendants for the subject diabetes medications;

l. Written and oral communications to payors, like Baltimore, regarding the processes through which the subject diabetes medications were chosen for inclusion on formularies;

m. Written and oral communications with government agencies misrepresenting the true nature of the Artificial Pricing Scheme and

deterring investigations into the PBM-Manufacturer Enterprises and subject diabetes medication pricing and formulary placement practices.

350. The precise dates of certain communications referenced above are alleged in this complaint. Because Defendants actively worked to conceal the Artificial Pricing Scheme from payors, like Baltimore, and the general public other dates cannot be alleged precisely without access to Defendants' books and records, which are in Defendants' custody and control.

E. Conduct of the PBM-Manufacturer RICO Enterprises' Affairs

351. Every Defendant participates in the operation and management of their respective PBM-Manufacturer Enterprises in which they conduct or participate in the conduct of the affairs of these association-in-fact RICO enterprises, directly or indirectly, in violation of 18 U.S.C. § 1962(c).

352. This participation in the PBM-Manufacturer Enterprises by Defendants includes:

a. PBM Defendants manage and directly control their formularies, determining how the subject diabetes medications are designated (or excluded).

b. Manufacturer Defendants set the list prices of their respective subject diabetes medications.

c. Manufacturer Defendants negotiate with PBM Defendants regarding the amount of rebates and other payments provided for the subject diabetes medications.

d. Manufacturer Defendants directly control the publication of the false and inflated list prices of the subject diabetes medications they manufacture, including by providing the false and inflated list prices to drug pricing compendia.

e. Manufacturer Defendants inform PBM Defendants of the inflated prices (and accordingly high profits) of their subject diabetes medications through their direct control of the distribution of marketing and sales materials.

f. In determining formulary treatment, PBM Defendants favor more expensive diabetes medications, excluding or treating less favorably more cost-effective diabetes medications, to increase access to and use of higher-priced medications in coordination with Manufacturer Defendants as such medications are more profitable for both PBM Defendants and Manufacturer Defendants.

g. PBM Defendants misrepresented to payors and the public the benefits and cost-savings related to the PBM Defendants' formularies and negotiations with Defendant Manufacturers through their direct control over the creation and distribution of marketing, sales, and other materials.

h. By negotiating the contracts governing the relationships between payors, like Baltimore, and the various PBM-Manufacturer Enterprises, the PBM Defendants directly control the relationships between payors and those entities.

i. By concealing and laundering the rebates and other payments from Manufacturers through affiliated entities, the PBM Defendants direct and control the PBM-Manufacturer Enterprises' Artificial Pricing Scheme to retain a large and undisclosed proportion of the rebates and other payments.

j. PBM Defendants distribute through U.S. mail and interstate wire facilities materials claiming that payments made from Manufacturer Defendants to PBM Defendants save payors, such as Baltimore, costs related to the subject diabetes drugs.

k. By publishing and promoting the false and inflated list prices without disclosing the degree to which these prices differ from the prices actually received as a result of rebates and other payments, the Manufacturer Defendants represented to payors, like Plaintiff, that the list prices of the subject diabetes medications were the result of fair market competition and reflected the actual prices realized by Defendants.

F. Defendants' Pattern of Racketeering Activity

353. Through a pattern of racketeering activity, including unlawful acts such as mail fraud, 18 U.S.C. § 1341, and wire fraud, 18 U.S.C. § 1343, Defendants have conducted and participated in the affairs of their respective PBM-Manufacturer Enterprises. In furtherance of the Artificial Pricing Scheme, Defendants' pattern of racketeering involved, at a minimum, thousands of instances of the use of U.S. mail or interstate wire facilities. Every one of those instances is "racketeering activity" per 18 U.S.C. § 1961(1), and, together, they represent a "pattern of racketeering activity" per 18 U.S.C. § 1961(5), in which Defendants intended to, and did, defraud payors, including Baltimore.

354. Every Defendant engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity through the Artificial Pricing Scheme by purposefully and falsely inflating the list prices of the subject diabetes medications; misrepresenting the extent and purpose of the rebates and other payments exchanged between the Manufacturer Defendants and PBM Defendants as well as the considerations involved in the

construction of the PBM Defendants' respective formularies; and by failing to disclose—indeed actively concealing—such practices to payors, including Baltimore.

355. Defendants' racketeering activities amounted to a common course of conduct, with similar patterns and purposes, intended to deceive payors, including Baltimore.

356. Each use of the U.S. mail and interstate wire facilities employed by Defendants as part of the Artificial Pricing Scheme was related, had similar shared purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Baltimore.

357. The pattern of racketeering activity engaged in by Defendants was for the purpose of conducting the ongoing business affairs of the respective PBM-Manufacturer Enterprises, with which each of them is associated in fact.

G. Defendants' Motive

358. The motive of each Defendant in establishing and operating the Artificial Pricing Scheme and conducting the affairs of the PBM-Manufacturer Enterprises was to falsely obtain sales of and profits from the subject diabetes medications and control the market for such medications.

359. As alleged above, the Artificial Pricing Scheme was designed to, and did, encourage the use of the subject diabetes medications, resulting in payors, like Baltimore, paying for these medications based on their false and inflated list prices. Manufacturer Defendants capitalized on the Artificial Pricing Scheme to obtain favorable treatment on drug formularies, resulting in additional sales and increased profits. PBM Defendants capitalized on the Artificial Pricing Scheme, which falsely inflated the prices paid for the subject diabetes medications by payors like Baltimore, increasing profits to the PBM Defendants in addition to the rebates and other payments received from the Manufacturer Defendants.

H. Harm Caused by the Artificial Pricing Scheme

360. Baltimore, like other payors, has been injured in its business or property by each PBM-Manufacturer Enterprise's violations of federal law and pattern of racketeering activity. These violations of law and pattern of racketeering activity were a direct and proximate cause of the injury to Baltimore.

361. As discussed above, the prices paid by payors, including Baltimore, are directly tied to the false and inflated list prices set as a result of the Artificial Pricing Scheme.

362. The PBM-Manufacturer Enterprises have control over and are responsible for the list prices on which payors', including Baltimore's, payments are based. No other entity in the supply change has control over or responsibility for those list prices.

363. Defendants collectively set the prices that payors, including Baltimore, paid for the subject diabetes medications.

364. During the relevant period, Express Scripts and CVS provided PBM services to Baltimore and benefited therefrom.

365. During the relevant period, Baltimore paid these PBMs for subject diabetes medications.

366. The PBM-Manufacturer Enterprises controlled and participated in the Artificial Pricing Scheme that was, as discussed above, directly responsible for the false and inflated list prices upon which the prices paid by payors, including Baltimore, are based.

367. Accordingly, Baltimore was damaged by the Artificial Pricing Scheme. Absent the false and inflated prices and misrepresentations employed by the PBM-Manufacturer Enterprises in furtherance of the Artificial Pricing Scheme, Baltimore, like other payors, would have paid less for the subject diabetes medications.

368. Baltimore's damages are distinct and separate from the many other victims—including other payors, beneficiaries, direct purchasers, and other consumers—of the PBM-Manufacturer Enterprises' Artificial Pricing Scheme.

369. By violating 18 U.S.C. § 1962(c), Defendants are jointly and severally liable to Baltimore for treble the damages sustained by Baltimore in addition to the costs of this action, including reasonable attorneys' fees.

370. Baltimore further seeks injunctive relief against Defendants pursuant to 18 U.S.C. § 1964(a) for the fraudulent misrepresentations regarding the list prices of the subject diabetes medications and their continuing actions to conceal and suppress material facts related to the false and inflated prices for the subject diabetes medications.

371. Absent injunctive relief, Defendants will continue conducting and maintaining the Artificial Pricing Scheme. Baltimore continues to purchase the subject diabetes medications, which are necessary for the health of its beneficiaries. Baltimore will, accordingly, have to continue to pay for the subject diabetes medications based on the false and inflated list prices. Injunctive relief is necessary to halt Defendants' continuing fraudulent, unfair, unconscionable, and inequitable conduct. Accordingly, Baltimore seeks an injunction preventing Defendants from continuing to misrepresent, conceal, and suppress material facts concerning their conduct and the perpetuation of the Artificial Pricing Scheme.

COUNT TWO

VIOLATIONS OF RICO, 18 U.S.C. § 1962(d) BY CONSPIRING TO VIOLATE 18 U.S.C. § 1962(c) (Against All Defendants)

372. Plaintiff refers to Paragraphs 1 through 371 above and incorporates the same herein by this reference as set forth in full.

373. 18 U.S.C. § 1962(d) prohibits "any person [from] conspir[ing] to violate any of the provisions of subsection (a), (b), or (c) of this section."

374. By agreeing and conspiring to violate 18 U.S.C. § 1962(c), as detailed above, Defendants have violated 18 U.S.C. § 1962(d).

375. The object of the Defendants' conspiracy is to conduct and/or participate in the Artificial Pricing Scheme.

376. As alleged above and in relation to the Civil Conspiracy claim alleged below, Defendants each knowingly agreed to facilitate the Artificial Pricing Scheme and have engaged in overt and predicate fraudulent racketeering acts in furtherance of the conspiracy. These include: (1) Defendants agreed to and did inflate the prices of the subject diabetes medications in lockstep to achieve an unlawful purpose; (2) Defendants agreed to and did make false or misleading statements or material omissions regarding increases to the subject diabetes medications; the true nature, purpose, and amounts of the rebates and other payments made from Manufacturing Defendants to PBM Defendants; and the PBM Defendants' formulary construction practices; and (3) the PBM Defendants agreed to, and did, request and receive higher list prices and greater and greater rebates and other payments in exchange for favorable formulary placement.

377. The above-described Defendant co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy give rise to an inference that they not only agreed to the objective of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c) but also that they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity.

378. Defendants have engaged in and continue to engage in the commission of overt acts, including the following unlawful racketeering predicate acts, which occurred on multiple instances:

a. Mail fraud in violation of 18 U.S.C. § 1341;

b. Wire fraud in violation of 18 U.S.C. § 1343; and

c. Unlawful activity in violation of 18 U.S.C. § 1952.

379. Defendants' conspiracy to violate the federal laws listed above and the effects thereof are continuing and will continue. Baltimore has been injured in its property by these violations as Baltimore has paid more for the subject diabetes medications than it would have but for Defendants' conspiracy.

380. By violating 18 U.S.C. § 1962(d), Defendants are jointly and severally liable to Baltimore for treble the damages sustained by Baltimore along with the cost of this action, including reasonable attorneys' fees.

COUNT THREE

CIVIL CONSPIRACY
(Against All Defendants)

381. Plaintiff refers to Paragraphs 1 through 380 above and incorporates the same herein by this reference as set forth in full.

382. Defendants' conduct in furthering and implementing the Artificial Pricing Scheme, as described in this Complaint, constituted a combination of two or more persons to use unlawful means to accomplish an overt tortious or unlawful act.

383. Defendants conduct was tortious and in agreement and/or in concert with each other in pursuit of a common design. At minimum, Defendants knew the conduct of the others

constituted a breach of their legal duties but still provided substantial assistance and/or encouragement in that conduct.

384. All Defendants encouraged, planned, assisted, and participated in the Artificial Pricing Scheme.

385. As alleged herein, Defendants aided and abetted one another in violating federal and Maryland law.

386. All Defendants agreed to, and did in fact, carry out acts in furtherance of the Artificial Pricing scheme that artificially inflated the price of the subject diabetes medicines to Baltimore's detriment.

387. The PBM Defendants each made a conscious commitment to participate in the Artificial Pricing Scheme.

388. The Manufacturer Defendants each agreed among themselves and with the PBM Defendants to purposefully inflate the prices of the subject diabetes medications, and that a large portion of those inflated prices would remit to the PBM Defendants as rebates and other payments.

389. In exchange for the inflated prices and corresponding rebates and other payments, the PBM Defendants agreed to, and did, provide Manufacturer Defendants preferential treatment in the PBMs' formularies for the subject diabetes medications.

390. The Defendants share a common purpose of perpetuating the Artificial Pricing Scheme. Alone, neither group of Defendants could have accomplished the scheme. The PBM Defendants, on the one hand, rely on the Manufacturer Defendants to inflate the list prices of the subject diabetes medications and provide the PBM Defendants with the rebates and other payments necessary for their profit. The Manufacturer Defendants, on the other hand, required the PBM Defendants to give the subject diabetes medications favorable treatment on their formularies so

that payors' beneficiaries would have access to and purchase the subject diabetes medications, generating unearned revenue on the artificially inflated prices of the drugs for all involved in the scheme.

391. The Artificial Pricing Scheme, as alleged throughout this Complaint, resulted from direct coordination, exchange of information, constant communication, and, most importantly, explicit agreements between the PBM Defendants and the Manufacturer Defendants.

392. The following indirect evidence further reflects the existence of Defendants' conspiracy to engage in the fraudulent conduct making up the Artificial Pricing Scheme:

a. Numerous government investigations, hearings, and inquiries have focused on or targeted the Artificial pricing scheme and the collusion of Manufacturer Defendants and PBM Defendants in causing the artificial inflation of the prices of diabetes medications, including:

- The Senate Finance Committee probe into the increased insulin prices and the conspiracy between Defendants culminating in the Grassley & Wyden Report.
- Hearings before the House Oversight and Reform Committee on PBM practices that, in part, concluded, "PBMs engage in self-benefiting, anticompetitive tactics which increase costs for consumers and harm patient care."[115]
- Hearings before the House Oversight and Reform Committee on the role of drug companies in raising prescription drug prices.

[115] *Hearing Wrap Up: Pharmacy Benefit Managers Prioritize Their Pocketbooks Over Patient Care*, House Oversight Comm. (May 23, 2023), https://oversight.house.gov/release/hearing-wrap-up-pharmacy-benefit-managers-prioritize-their-pocketbooks-over-patient-care%EF%BF%BC/.

- Civil investigation demands to both Manufacturer Defendants and PBM Defendants seeking information about the dramatic price increases of diabetes medications as part of investigations by several states including Texas and Washington (who noted the information received would be shared with California, Florida, Minnesota, New Mexico, and the District of Columbia).
- Requests from various elected representatives in Congress to the Justice Department and Federal Trade Commission for an investigation of Defendants' potential collusion.

b. Even in the face of the various investigations into their conduct, Defendants have refused to provide or provided incomplete and misleading information regarding the agreements, sales figures, and pricing structures that make up the Artificial Pricing Scheme.

c. The lockstep and extreme inflation to the price of the subject diabetes medications coincided with the consolidation of the PBM market and the PBM Defendants' increasing market share.

393. The Artificial Pricing Scheme, as alleged throughout this Complaint, resulted from direct coordination, exchange of information, constant communication, and, most importantly, explicit agreements between the PBM Defendants and the Manufacturer Defendants.

394. The Artificial Pricing Scheme, Defendants' conspiracy, and Defendants' actions, misrepresentations, and omissions in furtherance of it have caused or contributed to the damages suffered by Baltimore, which has been and continues to be damaged by overpaying for diabetes medications as a result of Defendants' unlawful conduct.

395. Defendants are jointly liable for the violations described in this Complaint by virtue of the conspiracy.

COUNT FOUR

MARYLAND ANTITRUST ACT, MARYLAND COMMERCIAL LAW CODE § 11-201 *ET SEQ.* (Against All Defendants)

396. Plaintiff refers to Paragraphs 1 through 395 above and incorporates the same herein by this reference as set forth in full.

397. The Maryland Antitrust Act provides that a person may not "[b]y contract, combination, or conspiracy with one or more other persons, unreasonably restrain trade or commerce." Md. Code Ann., Com. Law § 11-204(a)(1). The Act authorizes "[a] person whose business or property has been injured or threatened with injury by a violation of § 11-204 [to] maintain an action for damages or for an injunction or both against any person who has committed the violation regardless of whether the person maintaining the action dealt directly or indirectly with the person who has committed the violation." *Id.* § 11-209(b)(2)(i).

398. Baltimore is a "person" as defined by the Act. *Id.* §§ 11-201(f), 11-209(b)(1).

399. Defendants are "person[s]" as defined by the Act. *Id.* § 11-201(f).

400. As alleged at length above, the Artificial Pricing Scheme represents a conspiracy between Defendants to raise the prices of the subject diabetes medications, allowing Defendants to use supracompetitive pricing to earn massive and unjustified profits at the expense of Baltimore and other purchasers of insulin.

401. The relevant geographic market is the United States. The relevant product market is the market for insulin.

402. As alleged at length above, the prices for insulin across the Manufacturer Defendants have risen in lockstep. Indeed, "competitors" in the market have mirrored price increases "within days or even hours."[116]

403. Various aspects of the insulin market and supply chain make it conducive to conspiracy.

404. As an initial matter, the insulin market is highly concentrated; the Manufacturer Defendants control more than 90% of the insulin market within the United States.

405. The insulin market is not just oligopolistic, but there is also transparent pricing as to the list prices of the drugs. List price changes are published by manufacturers through drug pricing compendia and other sources.

406. The PBM services market in the United States is also highly concentrated; the PBM Defendants control approximately 80% of the PBM market within the United States.

407. Insulin is a classic example of an inelastic good. For those who need the drug, it is a critical necessity, and they cannot simply opt not to purchase the drug even when prices rise. Nor is there an incentive to buy more insulin when prices drop because taking too much insulin is itself dangerous. Additionally, because insurance pays for part of, if not the bulk of, the cost of insulin for those who are covered, end users are distanced from changes in the actual full price of the drug, and such changes accordingly have less effect on their purchasing behaviors.

408. Additionally, there are high barriers to entry for both potential new PBMs and Insulin manufacturers.

409. In regard to the high barriers to entry for insulin manufacturers, insulin is a biologic, which is more difficult and expensive to produce than other types of medications, such as those

[116]Grassley & Wyden Report, *supra* note 10 at 6; *see also* Figures 7 & 8.

made up of chemical compounds. Further, new manufacturers of insulin would be forced to avoid or challenge the existing manufacturers' patents regarding insulins, which, as previously alleged, have been extended through evergreening. Additionally, as alleged above, the creation of biosimilar or follow-on insulins is tedious, expensive, and resource intensive. Finally, a new manufacturer of insulin has to persuade the PBM Defendants to include their drugs on their formularies in order to access a large swath of customers. As alleged above, the PBM Defendants have actively excluded biosimilar insulins and insulins with lower list prices from their formularies, making them inaccessible to customers and preventing those products from gaining market share.

410. There are similarly high barriers to entry for new PBMs. PBMs' value proposition is that they represent large purchasing power and, as such, have greater leverage when negotiating with manufacturers, pharmacies, and distributors. Accordingly, PBMs promise that because of this leverage they can negotiate greater discounts for payors and insurers. New PBMs, by their nature, represent less purchasing power and, accordingly, have less leverage in negotiating with manufacturers and have less to promise new customers.

411. Defendants had strong motives to engage in the Artificial Pricing Scheme. Increasing the list prices of insulin has allowed for increased revenues for the PBM Defendants, whose fees, rebates, and other types of payment are typically based upon the list prices of medications. Further, increasing the list prices of insulin allowed for the Manufacturer Defendants to increase revenues and minimize the effects of increased rebates and other payments to PBM Defendants in exchange for favorable treatment on their formularies. Increasing the list prices of their insulins in lockstep allowed the Manufacturer Defendants to avoid undercutting each other for their collective benefit.

412. Absent any conspiracy, the Manufacturer Defendants' decisions to raise, rather than lower or maintain, insulin prices are inexplicable.

413. Indeed, as alleged above, the Manufacturer Defendants' typical justification for high prices—"Research and Development" costs—was rejected by both the House Oversight Committee Report and Grassley & Wyden Report.[117]

414. The costs of producing insulin are low, and the lockstep price changes are not correlated to any corresponding increase in costs or demand.

415. Further, given the Manufacturer Defendants' supracompetitive pricing, it would have been in any of the Manufacturer Defendants' best interest to reduce prices to attempt to capture more market share.

416. Defendants had plentiful opportunities to negotiate, agree to, and manage the Artificial Pricing Scheme and conspiracy through their involvement and participation in both PCMA and PhRMA.

417. Accordingly, as described above, Defendants engaged in a conspiracy, through arrangements and agreements between Manufacturer Defendants and PBM Defendants, to inflate the price of insulin. This conspiracy includes the agreements between Manufacturer Defendants to raise prices in lockstep and the agreements between Manufacturer Defendants and PBM Defendants to increase list prices in exchange for rebates and other payments funneled back to the PBM Defendants that resulted in supracompetitive prices for payors. Each of these agreements is an unreasonable restraint of trade in violation of the Maryland Antitrust Act.

[117]Grassley & Wyden Report, *supra* note 10 at 17; *see* Oversight Report, *supra* note 52 at 164.

418. Any procompetitive benefit to Defendants' conspiracy and agreements restraining trade—if it exists—is manifestly outweighed by the anticompetitive effects, most notably the supracompetitive prices of insulin.

419. As a result of their violations of the Maryland Antitrust Act, Defendants are liable to Baltimore for treble the damages sustained by Baltimore, the costs of this action, including reasonable attorneys' fees, and any and all other remedies deemed appropriate by the Court and authorized by law.

COUNT FIVE

MARYLAND CONSUMER PROTECTION ACT, MARYLAND COMMERCIAL LAW CODE § 13-101 *ET SEQ.* (Against Defendants Eli Lilly, Novo Nordisk, Sanofi, CVS, & Express Scripts)

420. Plaintiff refers to Paragraphs 1 through 419 above and incorporates the same herein by this reference as set forth in full.

421. Plaintiff brings this claim against Manufacturer Defendants: Eli Lilly, Novo Nordisk, and Sanofi as well as CVS and Express Scripts, who provided PBM services to Baltimore.

422. The Maryland Consumer Protection Act ("CPA") bars "unfair, abusive, or deceptive trade practices" in the sale or offer for sale of any consumer good or consumer services. Md. Code Ann., Com. Law § 13-303(1)-(2). The Act authorizes an action by "any person" "to recover for injury or loss sustained by him as the result of a practice prohibited by this title." *Id.* § 13-408(a).

423. Baltimore is a "person" and "consumer" as defined in the CPA. *Id.* § 13-101(c), (h).

424. Defendants are each a "person" as defined in the CPA. *Id.* § 13-101(c).

425. Insulin is a "consumer good" as defined in the CPA. *Id.* § 13-101(d)(1)-(2).

426. Unfair, abusive, or deceptive trade practices include any:

a. "False, falsely disparaging, or misleading oral or written statement, visual description, or other representation of any kind which has the capacity, tendency, or effect of deceiving or misleading consumers." *Id.* § 13-301(1).

b. "Representation that: Consumer goods, consumer realty, or consumer services have a sponsorship, approval, accessory, characteristic, ingredient, use, benefit, or quantity which they do not have." *Id.* § 13-301(2)

c. "Failure to state a material fact if the failure deceives or tends to deceive." *Id.* § 13-301(3).

d. "Deception, fraud, false pretense, false premise, misrepresentation, or knowing concealment, suppression, or omission of any material fact with the intent that a consumer rely on the same in connection with: (i) The promotion or sale of any consumer goods, consumer realty, or consumer service . . . ." *Id.* § 13-301(9).

427. Defendants' conduct in executing the Artificial Pricing Scheme constitutes unfair and deceptive trade practices prohibited by the CPA. This conduct includes, at minimum:

a. Manufacturer Defendants' publication of prices for the subject diabetes medications that misrepresented the true cost of those medications. Manufacturer Defendants held these prices out as the actual price for the subject diabetes medications knowing the prices were grossly inflated, in excess of the cost of the medications, and not reflective of the actual price the Manufacturers received for the medications.

b. Manufacturer Defendants misrepresented and concealed, suppressed, and omitted the reasons for increased list prices of the subject diabetes medications.

c. Express Scripts and CVS deceptively used Manufacturer Defendants' inflated list prices to calculate the prices and fees paid by payors, such as Baltimore, and concealed, suppressed, or omitted information regarding the inflated nature of the list prices being charged.

d. Express Scripts and CVS misrepresented their role in setting the prices paid for the subject diabetes medications, including by claiming they were working to generate savings for payors and beneficiaries. Express Scripts and CVS concealed, suppressed, and failed to disclose their role in causing the increase in diabetes medication prices by providing favorable formulary placement in exchange for higher list prices and greater rebates and other payments.

e. Express Scripts and CVS misrepresented and concealed, suppressed, and failed to disclose the amount and nature of the rebate and other payments received from the Manufacturer Defendants.

428. Express Scripts and CVS's unfair and deceptive conduct was done with the knowledge, consent, and cooperation of the Manufacturer Defendants.

429. The Manufacturer Defendants' unfair and deceptive conduct was done with the knowledge, consent, and cooperation of Express Scripts and CVS.

430. Defendants' misrepresentations had the tendency to, and did, deceive consumers, including Baltimore.

431. Defendants' unfair and deceptive conduct continues to this day. And Defendants' misrepresentations about the true prices of the subject diabetes medications continue to cause Baltimore to purchase these medications at an excessive and inflated price. Unless stopped, these violations will continue to harm Baltimore and other payors.

432. Every purchase of the subject diabetes medications at inflated prices caused by the Artificial Pricing Scheme constitutes its own violation of the CPA, and Baltimore has suffered harm by paying for the subject diabetes medications in these purchases. This harm includes the amounts overpaid for the subject diabetes medications.

433. As a result of their violations of the CPA, Defendants are liable to Baltimore for damages, in an amount to be proven at trial, attorneys' fees, costs, and any and all other remedies deemed appropriate by the Court and authorized by law.

COUNT SIX

UNJUST ENRICHMENT
(Against Defendants Eli Lilly, Novo Nordisk, Sanofi, CVS, & Express Scripts)

434. Plaintiff refers to Paragraphs 1 through 433 above and incorporates the same herein by this reference as set forth in full.

435. This claim is alleged in the alternative to Baltimore's claims for legal relief.

436. Defendants have benefitted from the Artificial Pricing Scheme by setting prices for, selling, and negotiating rebates and other payments for diabetes medications sold at excessive and inflated prices.

437. Defendants received and retained benefits from Baltimore, including Baltimore's payments for the costs of the subject diabetes drugs over their fair market value and the PBM Defendants' retention of rebates and other payments that should have been remitted to Baltimore, resulting in inequity.

438. Defendants know they have received such benefits from Baltimore.

439. It would be inequitable and unconscionable for Defendants to retain these benefits.

440. Baltimore is accordingly entitled to disgorgement of the benefit and restitution, rescission, or any and all other relief necessary to restore Baltimore to that which it is entitled.

VII. PRAYER FOR RELIEF

441. WHEREFORE, Plaintiff prays for entry of judgment against the Defendants for the relief requested herein and to any other relief Plaintiff may otherwise be entitled, including, but not limited to:

a. A determination that Defendants have violated RICO, have conspired to violate RICO, have engaged in civil conspiracy, have been unjustly enriched, and have violated the Maryland Consumer Protection Act and Maryland Antitrust Act;

b. Judgement in favor of Plaintiff and against Defendants for damages in excess of $75,000 and in the specific amount to be proven at trial;

c. Injunctive relief enjoining defendants from continuing to participate in the wrongful conduct alleged;

d. An award of attorneys' fees and costs of suit to Plaintiff as provided by law;

e. An award of pre- and post-judgment interest as provided by law;

f. An award of restitution, disgorgement, and any other legal and equitable relief to which Plaintiff is entitled; and

g. An award of any further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

VIII. JURY DEMAND

Plaintiff demands trial by jury on all issues so triable.

Dated: March 18, 2024

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